IN THE CIRCUIT COURT
OF THE NINETEENTH JUDICIAL DISTRICT
LAKE COUNTY, ILLINOIS COUNTY

COUNTY OF LAKE, MICHAEL NERHEIM, LAKE COUNTY STATE'S ATTORNEY, MARK C. CURRAN, JR., LAKE COUNTY SHERIFF, DR. HOWARD COOPER, LAKE COUNTY CORONER, AND THE COUNTY OF LAKE IN THE NAME OF THE PEOPLE OF THE STATE OF ILLINOIS.

Plaintiffs,

vs.

PURDUE PHARMA L.P., PURDUE PHARMA, INC.; THE PURDUE FREDERICK COMPANY INC.; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS INC.; AMERICAN ACADEMY OF PAIN MEDICINE; THE AMERICAN GERIATRICS SOCIETY; and AMERICAN PAIN SOCIETY.

Defendants.

Civil Action No.: 17 CH 1680

FILED

DEC 21 2017

Eric Cartwright Weinstein
CIRCUIT CLERK

Complaint

PRELIMINARY STATEMENT

1. The County of Lake; Michael Nerheim, Lake County State's Attorney; Mark C. Curran, Jr., Lake County Sheriff; Dr. Howard Cooper, Lake County Coroner; and the County of Lake in the name of the People of the State of Illinois (collectively, "Lake County" or "the County") bring this action to hold accountable Defendants Purdue Pharma, L.P.; Purdue Pharma, Inc.; the Purdue Frederick Company Inc., Teva Pharmaceuticals USA, Cephalon, Inc., Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica Inc., Johnson & Johnson, Endo Health Solutions Inc., and Endo Pharmaceuticals Inc. (collectively, the "Manufacturing Defendants") for their campaign of unfairly, deceptively, and fraudulently marketing prescription opioids in Lake County, and to seek redress to address the epidemic of opioid use, abuse, addiction, and death they caused.

2. Defendants American Academy of Pain Medicine ("AAPM"), American Geriatric Society ("AGS"), and American Pain Society ("APS") (together referred to as "Front Group Defendants"), which are sued for injunctive relief only, worked with the Manufacturing Defendants to promote opioids to doctors and patients, including elderly patients, as appropriate and safe for long-term use to treat chronic pain, such as arthritis and low back pain. With significant financial support from and the direct involvement of these manufacturers, the Front Group Defendants published treatment guidelines, continuing medical education programs, and other materials that deceptively promoted the use of opioids for chronic pain. Because of their seeming objectivity and non-profit, public service missions, their promotional activity carried greater weight and buttressed Manufacturing Defendants' own marketing.

3. Prescription opioids are narcotics. They are derived from and possess properties similar to opium and heroin, and they are regulated as controlled substances. While opioids can dampen the perception of pain, they also can create an addictive, euphoric high. At higher doses,

they can slow the user's breathing, causing potentially fatal respiratory depression. Most patients receiving more than a few weeks of opioid therapy will experience severe withdrawal symptoms—including severe anxiety, nausea, headaches, tremors, delirium, and pain—if opioid use is delayed or discontinued. When using opioids continuously, patients grow tolerant to their analgesic effects—requiring progressively higher doses and increasing the risks of withdrawal, addiction, and overdose.

4. Because the medical community recognized these dangers, they originally used opioids cautiously and sparingly, typically only for short-term acute pain—where brief use limited the need for escalating doses and the risk of addiction—or for palliative (end-of-life) care.[1] Consequently, the market for prescription opioids was sharply constrained.

5. As Purdue developed OxyContin in the mid-1990s, it knew that to expand its market and profits, it needed to change the perception of opioids to permit and encourage the use of opioids long-term for widespread chronic conditions like back pain, migraines, and arthritis. Purdue, then joined by Teva, Janssen, and Endo and aided by the Front Group Defendants, began to promote opioids as safe, effective, and appropriate for even long-term use for routine pain conditions. As part of this strategy, Defendants misrepresented the risk of addiction for pain patients as modest, manageable, and outweighed by the benefits of opioid use.

6. Specifically, Defendants told prescribers and patients that:

a. patients receiving opioid prescriptions for pain typically would not become addicted, and that doctors could use screening tools to exclude patients who might.

b. patients who did appear addicted were not; they were "pseudoaddicted" and should be given more opioids.

[1] In this Complaint, "chronic pain" means non-cancer pain lasting three months or longer.

c. opioids relieved pain when used long-term, without any studies to support this claim and without disclosing the lack of evidence that opioids are safe or effective long-term or that opioids posed greater risks at the high doses required as patients developed tolerance.

d. opioids would improve patients' function and quality of life, while trivializing or omitting the many adverse effects of opioids that diminish patients' function and quality of life.

7. In addition, Purdue Pharma told doctors that OxyContin provided 12 hours of relief when Purdue knew that, for many patients, it did not. Its "end-of-dose failure" increased the risk of addiction by fueling the boom-and-bust cycle of pain and anxiety as the drug wore off, followed by relief when a patient took her next pill.

8. Faced with a rising tide of opioid addiction, overdose, and death—precisely the risks that they denied in their marketing—Purdue and Endo falsely promoted abuse-deterrent opioids as hard to abuse, impossible to crush, and superior to non-abuse deterrent alternatives. But the "abuse-deterrent" features of their opioids could be easily defeated and did not limit oral abuse (the most common form of abuse).

9. Defendants' conduct already has already caused incalculable damage to County residents whose lives were ended by or lost to opioid addiction and their loved ones. The struggles of one Beach Park family, among others, was told in a powerful, recent HBO documentary, *Warning: This Drug May Kill You.*

10. Stephany Gay never thought she would become a heroin addict. She was never in trouble, and nor were her friends. When she was 16-years old, she was given opioids for recurring kidney stones—Dilaudid, OxyContin, Purdue Pharma's flagship product, and Vicodin. (Purdue recently sought and obtained approval for OxyContin to be prescribed to children as young as 12, although adolescents prescribed opioids are more likely to misuse opioids as adults.)

11. Stephany's story unfolds in the same way as countless patients in Lake County and across the country. She began taking extra pills "here and there." She shared them with her sister, Ashley, when she had headaches or cramps or needed help to sleep. Stephany did not know that she could become addicted, and thought that because a doctor gave her the drugs, they "could not be that bad." She faked pain to get extra prescriptions and soon was taking 20 pills a day, using a month's supply in two days. She felt sick when she stopped taking the pills.

12. When Stephany's doctor refused to prescribe any more opioids, she began buying them from friends. When that became too expensive, she turned to heroin. Rather than buying 15 pills for $5 each to get her through a day, a $10 bag of heroin would last for three. At first, Stephany and Ashley only snorted heroin, vowing that they would never turn to needles, but a year later, Stephany was shooting heroin in her face, neck, chest, and palms, sleeping all day, waking up sick, and needing more. Before heroin, she was a stay-at-home mother with a 2-year old daughter, a house, and a "perfect life." She lost all of that—and Ashley—to an overdose when she relapsed after treatment.

13. Stephany's mother has adopted Stephany's young daughter, who already has learned where to find Narcan, the antidote to an opioid overdose, and how to use it if Stephany needs it.

14. Through Lake County's "A Way Out" program, Stephany was able to seek help through a County police station, without fear of prosecution. She entered, but did not complete, an in-patient addiction treatment program, and struggles through relapses to break the hold of her addiction.

15. Measured by sales, Defendants' scheme was resoundingly successful. Chronic opioid therapy—the prescribing of opioids long-term to treat chronic pain—has become a

commonplace, and often first-line, treatment. In 2015, on an average day, more than 650,000 opioid prescriptions were dispensed in the U.S. While previously a small minority of opioid sales, today between 80% and 90% of opioids (measured by weight) used are for chronic pain. This is true for Lake County, too, where more than 90% of opioids paid for through the County's health benefits plan were for long-term prescribing.

16. As a direct and foreseeable result of Defendants' conduct, Lake County has been swept up in what the CDC called a "public health epidemic" and what the U.S. Surgeon General deemed an "urgent health crisis."[2] The increased volume of opioid prescribing correlates directly to skyrocketing addiction, overdose, and death; black markets for diverted prescription opioids; and a corresponding rise in heroin and fentanyl abuse by individuals, like Stephany, who could no longer legally acquire or afford prescription opioids.

17. Thus, rather than compassionately helping patients, this explosion in opioid use—and Defendants' profits—has come at the expense of chronic pain patients. As the then Centers for Disease Control ("CDC") director concluded: "We know of no other medication routinely used for a nonfatal condition that kills patients so frequently."[3] From 1999 to 2015, more than 183,000 people died in the U.S. from overdoses related to prescription opioids—more than the number of Americans who died in the Vietnam War.

18. Lake County has not escaped this deadly trend. The County experienced 71 overdose deaths in 2016, 59 of which involved opioids, and the same number in 2017 as of November 1st. In 2015, 62 people overdosed on opioids. These numbers would have been

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[2] CDC, *Examining the Growing Problems of Prescription Drug and Heroin Abuse* (Apr. 29, 2014), available at http://www.cdc.gov/washington/testimony/2014/t20140429.htm;. Vivek H. Murthy, *Letter from the Surgeon General*, August 2016, available at http://turnthetiderx.org.

[3] *Id.*

considerably higher but for the 200 lives saved by the County's administration of Narcan to overdose victims (not including those rescued by local fire and emergency medical services).

19. Many of those who survive will battle addiction for the rest of their lives. Up to one in four patients who receive prescription opioids long-term for chronic pain in primary care settings struggles with addiction. In 2014, almost 2 million Americans were addicted to prescription opioids and another 600,000 to heroin.

20. Lake County opioid addiction treatment programs are overwhelmed by the growing demand for opioid addiction treatment. For example, NICASA, a not-for-profit organization providing addiction treatment services in the County, is currently experiencing their longest waiting list ever for residential treatment. Of those seeking residential treatment, up to 75% of them are opioid users. Treatment centers in the County are also seeing an increase in heroin-using clients, most of whom started with prescription opioids.

21. Lake County offers its own in-patient and outpatient substance abuse treatment programs. The County spent roughly $900,000 in local tax funds in 2017 on addiction treatment in 2017, and will spend over $1 million in 2018. In addition, the County has developed a pioneering program, A Way Out, a pre-arrest diversion program that encourages County residents with addiction to seek treatment services through 14 participating police departments in the County. Since June 2016, when the program was launched, A Way Out has connected 170 County residents to addiction treatment and recovery services. Seventy-five percent of those entering A Way Out use opioids.

22. The County also has experienced an increase in drug-related crimes. One independent analysis estimates the cost to the County of drug-related property offenses, such as

burglary and theft, amounted to $4.2 million in 2014 alone. These are just a few of the numerous costs borne by Lake County.

23. Defendants' conduct has violated, and continues to violate, the Illinois Consumer Fraud Act ("ICFA"), 815 ILCS 505/1, *et seq.*, the Uniform Deceptive Trade Practices Act ("UDAP"), 815 ILCS 510/1 *et seq.*, and the Illinois Drug Dealer Liability Act, 740 ILCS 57/5 *et seq.* Additionally, Defendants' conduct constitutes Insurance Fraud under 720 ILCS § 5/17-10.5(a)(1), fraud, fraudulent misrepresentation, and unjust enrichment. Accordingly, the County seeks injunctive relief, civil penalties, restitution, damages, and any other legal and equitable relief within this Court's powers to redress and halt these unfair, deceptive, and unlawful practices.

PARTIES

1. Plaintiffs

24. Plaintiff County of Lake is a body politic and corporate and a unit of local government organized and existing under the Constitution and laws of the State of Illinois, with its seat of government in Waukegan, IL 60085.

25. Michael Nerheim is the duly elected State's Attorney for Lake County. Mark C. Curran, Jr. is the duly elected Sheriff for Lake County. Dr. Howard Cooper is the duly elected coroner of Lake County. Each of these County officials are named plaintiffs in their official capacity.

2. Defendants

26. Purdue Pharma, L.P. is a limited partnership organized under the laws of Delaware. Purdue Pharma, Inc. is a New York corporation with its principal place of business in Stamford, Connecticut. The Purdue Frederick Company Inc. is a New York corporation with its

principal place of business in Stamford, Connecticut. In 2007, Purdue and three of its executives pleaded guilty to federal criminal charges for deceptively marketing opioids.

27. Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin, MS Contin, Dilaudid and Dilaudid-HP, Butrans, Hysingla ER in the United States and in Lake County.[4] OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual sales of OxyContin have fluctuated between $2 and $3 billion. Nationwide, OxyContin constitutes roughly 25% of the entire market, by spending, for prescription opioids.

28. Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business in North Wales, Pennsylvania. Teva USA acquired Cephalon, Inc. in October 2011. Cephalon, Inc. ("Cephalon") is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. Teva USA and Cephalon work together closely to market and sell Cephalon products in the United States and Summit County. Teva USA also sells generic opioids in the United States and Summit County, including generic opioids previously sold by Allergan plc, whose generics business Teva Pharmaceutical Industries Ltd., Teva USA's parent company based in Israel, acquired in August 2016.

29. Teva manufactures, promotes, sells, and distributes opioids such as Actiq, a fentanyl lollipop, and Fentora, a dissolving pill, in the U.S. and Lake County. Actiq and Fentora have been approved by the U.S. Food and Drug Administration ("FDA") only for the "management of breakthrough cancer pain in patients 16 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain." In 2008, Cephalon pled guilty to a criminal violation of the Federal Food, Drug and

[4] Purdue also obtained approval to market Targiniq ER (oxycodone hydrochloride and naloxone hydrochloride) in 2014, but it has not actively marketed it.

Cosmetic Act for its misleading promotion of Actiq and two other drugs and agreed to pay $425 million.

30. Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of Johnson & Johnson ("J&J"), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. Ortho-McNeil-Janssen Pharmaceuticals, Inc., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. Janssen Pharmaceutica Inc., now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals' stock and corresponds with the FDA regarding Janssen's products. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals' drugs and Janssen's profits inure to J&J's benefit. These parties are collectively referred to as "Janssen."

31. Janssen manufactures, promotes, sells, and distributes drugs in the U.S. and Lake County, including the opioid Duragesic. Before 2009, Duragesic accounted for at least $1 billion in annual sales. Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta and Nucynta ER. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014.

32. Endo Health Solutions Inc. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Endo Pharmaceuticals Inc. is a wholly-owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. These parties are collectively referred to as "Endo."

33. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydone, in the U.S. and Lake County. Opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012. Opana ER yielded $1.15 billion in revenue from 2010 and 2013, and it accounted for 10% of Endo's total revenue in 2012. Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the U.S. and Lake County, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc. On July 6, 2017, in response to an FDA request that Endo voluntarily withdraw the product from the market, the company announced that it would stop marketing and selling a reformulated version of Opana ER that it had marketed as abuse-deterrent.

34. The American Academy of Pain Medicine is a 501(c)(6) tax exempt organization with its principal place of operation in Chicago, Illinois. According to its most recent Form 990 filings with the Internal Revenue Service, AAPM's purpose is to "optimize the health of patients and eliminate the major public health problem of pain by advancing the practice and the specialty of pain medicine."

35. The American Geriatrics Society is a 501(c)(3) tax exempt organization with its principal place of operations in New York, New York. According to its most recent Form 990 filing with the Internal Revenue Service, AGS's purpose is to [i]mprove[] the health, independence[, and] quality of life of all older people[.]"

36. The American Pain Society is a 501(c)(3) tax exempt organization with its principal place of operations in Chicago, Illinois. According to its most recent Form 990 filing with the Internal Revenue Service, APS's purpose is to "increase the knowledge of pain and transform public policy and clinical practice."

JURISDICTION AND VENUE

37. This court has jurisdiction over this matter under Ill. Const. art. VI, § 9.

38. Venue as to each Defendant is proper in this court under 735 ILCS 5/2-101, as the transactions and occurrences that form the basis for this Complaint occurred in Lake County, Illinois.

39. The State's Attorney does not represent or seek relief on behalf of consumers, either individually or as a class, but seeks restitution for the County's own spending pursuant to the statutory authority granted by 815 ILCS 505/7.

40. Because the State of Illinois is not a citizen for purposes of diversity jurisdiction and because the Complaint names two forum defendants, there is a lack of complete diversity, and because this action does not arise under federal law, no federal court can exercise subject matter jurisdiction over this case.

41. The State's Attorney has determined that this proceeding is in the public interest.

A. ADDITIONAL ALLEGATIONS COMMON TO ALL COUNTS

42. Until the mid-1990s, opioids were widely thought to be too addictive for use for chronic pain conditions, which would require long-term use of the drugs at increasingly high doses. For these conditions, the risks of addiction and other side effects outweighed any benefit from the drugs. Over the last two decades, Defendants turned that consensus on its head by denying the risk of addiction and overstating the benefits of using opioids long-term.

43. Through marketing that was as pervasive as it was deceptive, Defendants convinced health care providers both that the risks of long-term opioid use were overblown and that the benefits, in reduced pain and improved function and quality of life, were proven.

44. The result was that by the mid-2000s, the medical community had abandoned its prior caution, and opioids were entrenched as an appropriate—and often the first—treatment for chronic pain conditions. Manufacturing Defendants not only marketed opioids for chronic pain conditions, but also targeted primary care physicians (along with nurse practitioners and physician assistants), who were most likely to see patients with chronic pain conditions and least likely to have the training and experience to evaluate both Defendants' marketing and patients' pain conditions. (Nearly half of all doctors visited by Manufacturing Defendants' sales representatives in the County, according to publicly available sources, were general practitioners.)

45. Defendants' deceptive marketing created a cadre of doctors who looked for pain and treated it with opioids, which created an even broader cohort of patients who expected and received opioids. This laid the groundwork for today's epidemic of opioid addiction, injury, and death in Lake County.

B. DEFENDANTS FALSELY TRIVIALIZED, MISCHARACTERIZED, AND FAILED TO DISCLOSE THE KNOWN, SERIOUS RISK OF ADDICTION.

46. Manufacturing Defendants spent hundreds of millions of dollars on promotional activities and materials, including advertising, websites, and in-person sales calls, that falsely denied or trivialized the risk of addiction and overstated the benefits of opioids. They also relied upon seminars, treatment guidelines, and other publications and programs by patient advocacy groups, professional associations (including the Front Group Defendants), and physicians that were unsupported and misleading, but seemed independent and therefore credible.

47. Manufacturing Defendants rely heavily on their sales representatives to convey their marketing messages and materials to prescribers in targeted, in-person settings. Not surprisingly, all of the Manufacturing Defendants' sales representatives visited prescribers in

Lake County. Sales representatives from Purdue and Teva were the most frequent visitors to County prescribers where there was a meal reimbursement with at least 225 and 235 visits, respectively, between the third quarter of 2013 and fourth quarter of 2016. These visits frequently coincided with payments to the prescriber for "promotional speaking," "food and beverage," "consulting," "travel and lodging," "honoraria," and "education."

48. The U.S. Senate Homeland Security & Governmental Affairs Committee recently issued a Staff Report which noted the link between drug maker payments to prescribers and physician prescribing practices. It found that "a clear link exists between even minimal manufacturer payments and physician prescribing practices."[5] The Report quotes findings that "doctors who received industry payments were two to three times as likely to prescribe brand-name drugs at exceptionally high rates as others in their specialty."

49. To ensure that sales representatives deliver the desired messages to prescribers, Manufacturing Defendants direct and monitor their sales representatives through detailed action plans, trainings, tests, scripts, role-plays, supervisor tag-alongs, and review of representatives' notes (known as "call notes") from each visit. These Defendants likewise required their sales representatives to use sales aids reviewed, approved, and supplied by the companies. They further ensured marketing consistency nationwide through national and regional sales representative training. Thus, the companies' sales forces in the County carried out national marketing strategies, delivering centrally scripted messages and materials that were consistent across the country.

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[5] Staff Report, *Fueling an Epidemic, Insys Therapeutics and the Systemic Manipulation of Prior Authorization.*

50. Manufacturing Defendants also used "key opinion leaders" ("KOLs")—experts in the field who were especially influential because of their reputations and seeming objectivity—to deliver paid talks and continuing medical education programs (or "CMEs") that provided information about treating pain and the risks, benefits, and use of opioids. These KOLs received substantial funding and research grants from these Defendants, and the CMEs were often sponsored by Defendants—giving them considerable influence over the messenger, the message, and the distribution of the program. Only doctors supportive of the use and safety of opioids for chronic pain received these funding and speaking opportunities, which were not only lucrative, but also helped doctors build their reputations and bodies of work. One leading KOL, Dr. Russell Portenoy, subsequently acknowledged that he gave lectures on opioids that reflected "misinformation" and were "clearly the wrong thing to do."

51. In addition to talks and CMEs, these KOLs served on the boards of patient advocacy groups and professional associations, such as the American Pain Foundation and Defendants APS and AAPM, which were also able to exert greater influence because of their seeming independence. Manufacturing Defendants exerted influence over these groups by providing major funding directly to them, as well. These "front groups" for the opioid industry put out patient education materials and treatment guidelines that supported the use of opioids for chronic pain, overstated their benefits, and understated their risks. In many instances, Manufacturing Defendants distributed these publications to prescribers or posted them on their websites.

52. Neither these third-party, unbranded materials, nor the marketing messages or scripts relied on by Manufacturing Defendants' sales representatives, were reviewed or approved

by the FDA. All of the messages described below were disseminated to Lake County prescribers and patients.

1. Minimizing or mischaracterizing the risk of addiction

53. This created the dangerously misleading impressions that: (1) patients receiving opioid prescriptions for chronic pain would not become addicted, (2) patients at greatest risk of addiction could be identified, and (3) all other patients could safely be prescribed opioids.

54. Manufacturing Defendants' sales representatives regularly omitted from their sales conversations with prescribers in Lake County any discussion of the risk of addiction from long-term use of opioids. Indeed, Lake County doctors confirmed in interviews that sales representatives who visited them did not discuss or bring up addiction, though one doctor recalled receiving a study that found that less than 1% of patients prescribed opioids became addicted.

55. Manufacturing Defendants also undermined evidence that opioids are addictive by suggesting or stating that the risk of addiction is limited to high-risk patients. Manufacturing Defendants encouraged doctors in Lake County to prescribe their opioids to the right patients or "appropriate" patients, which was meant, and understood, to mean patients who were not likely to become addicted.

56. Manufacturing Defendants' sales representatives also regularly failed to disclose to prescribers in the County the difficulty of withdrawing from opioids. For example, a 2011 non-credit educational program sponsored by Endo, entitled Persistent Pain in the Older Adult, claimed that withdrawal symptoms, which make it difficult for patients to stop using opioids, could be avoided by tapering a patient's opioid dose over ten days. Most patients who are dependent upon or addicted to opioids will experience withdrawal, characterized by intense physical and psychological effects, including anxiety, nausea, headaches, and delirium, among

others. This difficulty in terminating use can leave many patients unwilling or unable to give up opioids and heightens the risk of addiction.

57. Manufacturing Defendants falsely portrayed "true" addiction in its narrowest form. *Providing Relief, Preventing Abuse*, a pamphlet published by Purdue in 2011 for prescribers and law enforcement, shows pictures of the signs of injecting or snorting opioids—skin popping, track marks, and perforated nasal septa—under the heading "Indications of Possible Drug Abuse." These depictions misleadingly reassured doctors that, in the absence of those extreme signs, they need not worry that their patients are abusing or addicted to opioids. But Purdue knew that individuals who resort to these extremes are uncommon; they far more typically become dependent and addicted through oral use. According to briefing materials Purdue submitted to the FDA in October 2010, OxyContin was used non-medically by injection as little as 4% of the time. Purdue made *Providing Relief, Preventing Abuse* available to sales representatives to show to or leave with prescribers, including, on information and belief, prescribers in the County.[6]

58. Purdue also disseminated misleading information about opioids and addiction through the American Pain Foundation ("APF"), over which Purdue and other Manufacturing Defendants exercised control.[7] For example, *A Policymaker's Guide to Understanding Pain &*

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[6] Unless otherwise noted, allegations based on "information and belief" are based on the uniformity of Defendants' nationwide strategy and practices, which would reasonably be expected to apply in Lake County in the same manner as elsewhere.

[7] In practice, APF operated in close collaboration with opioid makers. On several occasions, representatives of the drug companies, often at informal meetings, suggested activities and publications for APF to pursue, which they then funded APF to pursue. Purdue was APF's second-biggest donor. The largest donor, from 2007 until APF closed its doors in 2012, was Endo, which provided more than half of APF's $10 million in total funding during that time period. Purdue grant letters informed APF that Purdue's contributions reflected the company's effort to "strategically align its investments in nonprofit organizations that share [its] business

Its Management, a 2011 APF publication that Purdue sponsored, claimed that pain generally had been "undertreated" due to "[m]isconceptions about opioid addiction." This guide also asserted, without basis, that "less than 1% of children treated with opioids become addicted" and perpetuated the concept of pseudoaddiction (*see* Section A.2, *infra*). Purdue provided substantial funding to APF and closely collaborated with APF in creating *A Policymaker's Guide.* On information and belief, based on Purdue's close relationship with APF and the periodic reports APF provided to Purdue about the project, Purdue had editorial input into *A Policymaker's Guide*. It is still available to County prescribers online.

59. Purdue also maintained a website from 2008 to 2015, *In the Face of Pain*, which downplayed the risks of chronic opioid therapy. Purdue deactivated this website in October 2015 following an investigation by the New York Attorney General. *In the Face of Pain* asserted that policies limiting access to opioids are "at odds with best medical practices" and encouraged patients to be "persistent" in finding doctors who will treat their pain. While a document linked from the website briefly mentioned opioid abuse, the site itself *never* mentioned the risk of addiction. At the same time, the website contained testimonials from several dozen physician "advocates" speaking positively about opioids. Eleven of these advocates received a total of $231,000 in payments from Purdue from 2008 to 2013—a fact notably omitted from the site.

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interests." Purdue also engaged APF as a paid consultant on various initiatives and deployed APF to lobby for its interests on Capitol Hill, for example, by opposing legislation that would have restricted the use of long-acting (but not short-acting) opioids, which would distinctly disadvantage Purdue.

The close relationship between APF and the drug company was not unique, but mirrors relationships between APF and Manufacturing Defendants. APF's clear lack of independence—in its finances, management, and mission—and its willingness to allow Defendants to control its activities and messages support an inference that each Manufacturing Defendant that worked with it was able to exercise editorial control over its publications.

60. Endo sponsored a website, Painknowledge.com, which claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted." Another Endo website, PainAction.com, stated: "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them."

61. Endo also distributed a pamphlet with the Endo logo entitled *Living with Someone with Chronic Pain*, which stated that: "Most health care providers who treat people with pain agree that most people do not develop an addiction problem." A similar statement appeared on the Endo website, www.opana.com.

62. Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which described as "myth" the claim that opioids are addictive, and asserted as fact that "[m]any studies show that opioids are *rarely* addictive when used properly for the management of chronic pain." This guide is still available online.

63. Janssen currently runs a website, *Prescriberesponsibly.com*, which claims that concerns about opioid addiction are "overestimated."

64. Manufacturing Defendants' efforts to trivialize the risk of addiction were, and remain, at odds with the scientific evidence. Studies have shown that at least 8-12%, and as many as 30-40% of long-term users of opioids experience problems with addiction. Addiction can result from the use of any opioid, "even at recommended dose"[8] and the risk increases with chronic (more than three months) of use.

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[8] *FDA announces safety labeling changes and postmarket study requirements for extended-release and long-acting opioid analgesics,* FDA (Sept. 10, 2013); *see also FDA announces enhanced warnings for immediate-release opioid pain medications related to risks of misuse, abuse, addiction, overdose and death,* FDA (Mar. 22, 2016),

2. Manufacturing Defendants Falsely Described Addiction as Pseudoaddiction and Dangerously Encouraged Doctors to Respond by Prescribing More Opioids.

65. Manufacturing Defendants covered up the occurrence of addiction by attributing it to a made-up condition they called "pseudoaddiction." Signs of addiction, including shopping for doctors willing to newly write or refill prescriptions for opioids or seeking early refills, actually reflected undertreated pain that should be addressed with more opioids—the medical equivalent of fighting fire by adding fuel.

66. Purdue, through its unbranded imprint *Partners Against Pain*,[9] promoted the concept of pseudoaddiction through at least 2013 on its website.

67. The Federation of State Medical Boards ("FSMB"), a trade organization representing the Illinois Division of Professional Regulation as well as others, finances opioid- and pain-specific programs through grants from Manufacturing Defendants. A 2004 version of the FSMB *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* ("FSMB Guidelines"), and the 2007 book adapted from them, *Responsible Opioid Prescribing*, advanced the concept of pseudoaddiction.

68. *Responsible Opioid Prescribing* was sponsored by Purdue, Endo, and Teva. The FSMB website described the book as the "leading continuing medical education (CME) activity for prescribers of opioid medications." *Responsible Opioid Prescribing* was distributed nationally and in Illinois.

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https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491739.htm.

[9] *Partners Against Pain* consists of both a website, styled as an "advocacy community" for better pain care, and medical education resources distributed to prescribers by the sales force. It has existed since at least the early 2000s and has been a vehicle for Purdue to downplay the risks of addiction from long-term opioid use. One early pamphlet, for example, answered concerns about OxyContin's addictiveness by claiming: "Drug addiction means using a drug to get 'high' rather than to relieve pain. You are taking opioid pain medication for medical purposes. The medical purposes are clear and the effects are beneficial, not harmful."

69. Janssen sponsored, funded, and edited the *Let's Talk Pain* website, which in 2009 stated: "pseudoaddiction . . . refers to patient behaviors that may occur when *pain is under-treated* . . . . Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management." This website was accessible online until May 2012.

70. Endo sponsored a National Initiative on Pain Control (NIPC) CME program in 2009 titled *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia*, which promoted pseudoaddiction by teaching that a patient's aberrant behavior was the result of untreated pain. Endo substantially controlled NIPC, an initiative run by the APF, by funding NIPC projects; developing, specifying, and reviewing its content; and distributing NIPC materials. APF internal documents show that APF viewed the NIPC as an "opportunity to generate new revenue" given Endo's funding commitment.

71. Manufacturing Defendants also promoted the concept of pseudoaddiction through Dr. Russell Portenoy, a leading KOL for the Manufacturing Defendants. In doing so, he popularized the concept and falsely claimed that pseudoaddiction is substantiated by scientific evidence.

72. The CDC Guideline for prescribing opioids for chronic pain, a "systematic review of the best available evidence" by a panel excluding experts without conflicts of interest, rejects the concept of pseudoaddiction. The Guideline nowhere recommends that opioid doses be increased if a patient is not experiencing pain relief. To the contrary, the Guideline explains that "[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-term use,"[10] and that physicians should "reassess[]

[10] CDC Guideline at 13.

pain and function within 1 month" in order to decide whether to "minimize risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a clear benefit."[11]

3. Overstating the efficacy of screening tools.

73. Manufacturing Defendants falsely instructed prescribers and patients that screening tools, patient contracts, urine drug screens, and similar strategies allow health care providers to safely prescribe opioids to patients, including patients predisposed to addiction, and failed to disclose the lack of evidence that these strategies actually work to mitigate addiction risk. By using screening tools, these Defendants advised doctors that they could identify patients likely to become addicted and safely prescribe to everyone else.

74. Such misrepresentations regarding safe opioid prescribing made health care providers more comfortable prescribing opioids to their patients and patients more comfortable starting chronic opioid therapy. These misrepresentations were especially insidious because Manufacturing Defendants aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. Moreover, these misrepresentations allowed doctors to believe opioid addiction was the result of other prescribers failing to rigorously manage and weed out problem patients, not a risk inherent to the drugs.

75. These Defendants conveyed these safe prescribing messages through their in-person sales calls to doctors. Interviews with Lake County doctors confirm that Manufacturing Defendants' sales representatives talked about identifying "appropriate patients" as a strategy for managing the risk of addiction, abuse, and diversion.

[11] *Id.* at 25.

76. Manufacturing Defendants also promoted screening tools as a reliable means to manage addiction risk in CME programs and scientific conferences, which would have been attended by and were available online, to County prescribers.

77. For example, Purdue sponsored a 2011 CME program titled Managing Patient's Opioid Use: Balancing the Need and Risk. This presentation deceptively instructed prescribers that screening tools, patient agreements, and urine tests prevented "overuse of prescriptions" and "overdose deaths." Purdue also funded a 2012 CME program called Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes. The presentation deceptively instructed doctors that, through the use of screening tools, more frequent refills, and other techniques, even high-risk patients showing signs of addiction could be treated with opioids.

78. Purdue used its involvement in the College on the Problems of Drug Dependence ("CPDD"), which promotes scientific research and professional development to support addiction prevention professionals, to promote the idea that addiction risk can be managed. A Purdue employee served on the CPDD board of directors. Purdue presented an outsized number of talks—with very different messages from non-Purdue talks—at CPDD conferences. One of Purdue's consistent themes is that "bad apple" patients, not opioids, are the source of the opioid crisis, and that once those patients are identified doctors can safely prescribe opioids without a risk of addiction. Hundreds of addiction treatment specialists from across the country and, upon information and belief, prescribers from the County, attended these conferences.

79. Endo paid for a 2007 supplement in the Journal of Family Practice written by a doctor who became a member of Endo's speakers bureau (doctors paid to give talks, typically reserved for the largest prescribers) in 2010. The supplement, entitled Pain Management

Dilemmas in Primary Care: Use of Opioids, emphasized the effectiveness of screening tools, claiming that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.

80. The CDC Guideline confirms the falsity of Manufacturing Defendants' claims about the utility of patient screening and management strategies in managing addiction risk. The Guideline notes that there are no studies assessing the effectiveness of risk mitigation strategies—such as screening tools or patient contracts—"for improving outcomes related to overdose, addiction, abuse, or misuse." The CDC Guideline recognizes that available risk screening tools "show insufficient accuracy for classification of patients as at low or high risk for [opioid] abuse or misuse" and counsels that doctors "should not overestimate the ability of these tools to rule out risks from long-term opioid therapy."[12]

C. MANUFACTURING DEFENDANTS OVERSTATED THE BENEFITS OF CHRONIC OPIOID THERAPY WHILE FAILING TO DISCLOSE THE LACK OF EVIDENCE SUPPORTING LONG-TERM USE.

1. Mischaracterizing the benefits of and evidence for long-term use

81. To convince prescribers and patients that opioids should be used to treat chronic pain, Defendants had to persuade them of a significant upside to long-term opioid use. Assessing existing evidence, the CDC Guideline found that there is "insufficient evidence to determine the long-term benefits of opioid therapy for chronic pain."[13] In fact, the CDC found that "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled

[12] CDC Guideline at 28 (emphasis added).

[13] *Id.* at 10.

randomized trials ≤ 6 weeks in duration)"[14] and that other treatments were more or equally beneficial and less harmful than long-term opioid use. The FDA, too, has recognized the lack of evidence to support long-term opioid use. In 2013, the FDA stated that it was "not aware of adequate and well-controlled studies of opioids use longer than 12 weeks."[15] As a result, the CDC recommends that opioids be used not in the first instance and only after prescribers have exhausted alternative treatments.

82. Nevertheless, upon information and belief, Defendants touted the purported benefits of long-term opioid use, while falsely and misleadingly suggesting that these benefits were supported by scientific evidence. No prescriber interviewed by Lake County indicated that Manufacturing Defendants disclosed the lack of evidence to support long-term opioid therapy for the treatment of chronic pain.

83. In addition and for example, Defendants AAPM and APS each received substantial funding from Manufacturing Defendants. Upon information and belief, Manufacturing Defendants exercised considerable influence over their work on opioids. Both organizations issued a consensus statement in 1997, *The Use of Opioids for the Treatment of Chronic Pain*, which endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low. The co-author of the statement, Dr. David Haddox, was at the time a paid speaker for Purdue and later became a senior executive for the company. KOL Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM's website until 2011 and was only removed from AAPM's website after a doctor complained.

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[14] *Id.* at 9.

[15] Letter from Janet Woodcock, M.D, Dir., Center for Drug Eval. and Research, to Andrew Kolodny, M.D. (Sept. 10, 2013).

84. A past president of the AAPM, Dr. Scott Fishman, who also served as a KOL for Manufacturing Defendants, stated that he would place the organization "at the forefront" of teaching that "the risks of addiction are . . . small and can be managed."[16]

85. AAPM and APS issued treatment guidelines in 2009 ("AAPM/APS Guidelines") which continued to recommend the use of opioids to treat chronic pain. Treatment guidelines, like the AAPM/APS Guidelines, were particularly important to Manufacturing Defendants in securing acceptance for chronic opioid therapy. They are relied upon by doctors, especially general practitioners and family doctors who have no specific training in treating chronic pain. Six of the twenty-one panel members who drafted the AAPM/APS Guidelines received support from Purdue, eight from Teva, nine from Janssen, and ten from Endo.

86. The AAPM/APS Guidelines promote opioids as "safe and effective" for treating chronic pain. The panel made "strong recommendations" despite "low quality of evidence" and concluded that the risk of addiction is manageable for patients, even with a prior history of drug abuse. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the Guidelines were influenced by contributions that drug companies, including Purdue, Endo, Janssen, and Teva, made to the sponsoring organizations and committee members.

87. Dr. Gilbert Fanciullo, now retired as a professor at Dartmouth College's Geisel School of Medicine, who served on the AAPM/APS Guidelines panel, has since described them as "skewed" by drug companies and "biased in many important respects," including its high

[16] Interview by Paula Moyer with Scott M. Fishman, M.D., Professor of Anesthesiology and Pain Medicine, Chief of the Division of Pain Medicine, Univ. of Cal., Davis (2005), available at http://www.medscape.org/viewarticle/500829.

presumptive maximum dose, lack of suggested mandatory urine toxicology testing, and claims of a low risk of addiction.

88. The AAPM/APS Guidelines are still available online, were reprinted in the *Journal of Pain*, and have influenced not only treating physicians, but also the body of scientific evidence on opioids. According to Google Scholar, they have now been cited at least 1,647 times in academic literature.

89. Additionally, AGS disseminated guidelines regarding the use of opioids for chronic pain in 2002 (*The Management of Persistent Pain in Older Persons*, hereinafter "2002 AGS Guidelines") and 2009 (*Pharmacological Management of Persistent Pain in Older Persons*, hereinafter "2009 AGS Guidelines"). The 2009 AGS Guidelines included the following recommendations: "All patients with moderate to severe pain . . . should be considered for opioid therapy (low quality of evidence, strong recommendation)," and "the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse."[17] These recommendations, which continue to appear on AGS's website, are not supported by any study or other reliable scientific evidence. Nevertheless, they have been cited 535 times in Google Scholar since their 2009 publication.

90. AGS contracted with Defendants Endo, Purdue, and Janssen to disseminate the 2009 Guidelines, and to sponsor CMEs based on them. These Defendants were aware of the content of the 2009 Guidelines when they agreed to provide funding for these projects. The 2009 Guidelines were released at the May 2009 AGS Annual Scientific Meeting in Chicago and first published online on July 2, 2009. AGS submitted grant requests to Defendants including

[17] Pharmacological Management of Persistent Pain in Older Persons, 57 J. Am. Geriatrics Soc'y 1331, 1339, 1342 (2009), *available at* http://www.americangeriatrics.org/files/documents/2009_Guideline.pdf.

Endo and Purdue beginning July 15, 2009. Internal AGS discussions in August 2009 reveal that it did not want to receive up-front funding from drug companies, which would suggest drug company influence, but would instead accept commercial support to disseminate the publication. However, by drafting the guidelines knowing that pharmaceutical company funding would be needed, and allowing these companies to determine whether to provide support only after they have approved the message, AGS ceded significant control to these companies. Endo, Janssen, and Purdue all agreed to provide support to distribute the guidelines.

91. According to one news report, AGS has received $344,000 in funding from opioid makers since 2009.[18] Five of 10 of the experts on the guidelines panel disclosed financial ties to Defendants, including serving as paid speakers and consultants, presenting CMEs sponsored by Defendants, receiving grants from Defendants, and investing in Defendants' stock. The Institute of Medicine recommends that, to ensure an unbiased result, fewer than 50% of the members of a guidelines committee should have financial relationships with drug companies.

92. Purdue, for example, also published misleading studies to enhance the perception that opioids are effective long-term for chronic pain conditions. One study asserts that OxyContin is safe and effective for the chronic pain condition osteoarthritis. The study, sponsored by Purdue, involved providing oxycodone for 30 days, and then randomizing participants and providing a placebo, an immediate release oxycodone with acetaminophen (like Percocet), or OxyContin. Only 107 of the 167 patients went on to the second phase of the study, and most who withdrew left because of adverse events (nausea, vomiting, drowsiness, dizziness, or headache) or ineffective treatment. Despite relating to a chronic condition, opioids were

[18] John Fauber & Ellen Gabler, *Narcotic Painkiller Use Booming Among Elderly*, Milwaukee J. Sentinel, May 30, 2012.

provided only short-term. The authors even acknowledge that the "results . . . should be confirmed in trials of longer duration to confirm the role of opioids in a chronic condition such as OA [osteoarthritis]."[19] Yet, the authors conclude that "[t]his clinical experience shows that opioids were well tolerated with only rare incidence of addiction and that tolerance to the analgesic effects was not a clinically significant problem when managing patients with opioids long-term."[20] This statement is not supported by the data—a substantial number of patients dropped out because of adverse effects, there was no reported data regarding addiction, and the study was not long-term.

93. Teva deceptively marketed its opioids Actiq and Fentora for chronic pain even though the FDA has expressly limited their use to the treatment of cancer pain in opioid-tolerant individuals.

94. Both Actiq and Fentora are extremely powerful fentanyl-based opioids. Neither is approved for or has been shown to be safe or effective for chronic pain. Indeed, the FDA expressly prohibited Teva from marketing Actiq for anything but cancer pain, and refused to approve Fentora for the treatment of chronic pain because of the potential harm, including the high risks of "serious and life-threatening adverse events" and abuse—which are greatest in non-cancer patients. The FDA also issued a Public Health Advisory in 2007 emphasizing that Fentora should only be used for cancer patients who are opioid-tolerant and should not be used for any other conditions, such as migraines, post-operative pain, or pain due to injury.

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[19] Jacques R. Caldwell, *et al.*, *Treatment of Osteoarthritis Pain with Controlled Release Oxycodone or Fixed Combination Oxycodone Plus Acetaminophen Added to Nonsteroidal Antiinflammatory Drugs: A Double Blind, Randomized, Multicenter, Placebo Controlled Trial*, 266.4 Journal of Rheumatology 862-869 (1999).

[20] *Id.*

95. Despite this, Teva has conducted a well-funded and deceptive campaign to promote Actiq and Fentora for chronic pain and other non-cancer conditions for which it was not approved, appropriate, or safe. As part of this campaign, Teva used CMEs, speaker programs, KOLs, journal supplements, and detailing by its sales representatives to give doctors the false impression that Actiq and Fentora are safe and effective for treating non-cancer pain, without disclosing the lack of evidence or the FDA's rejection of their use for chronic pain.

96. For example, Teva paid to have a CME it sponsored, Opioid-Based Management of Persistent and Breakthrough Pain, published in a supplement of Pain Medicine News in 2009. The CME instructed doctors that "clinically, broad classification of pain syndromes as either cancer- or noncancer-related has limited utility" and recommended Actiq and Fentora for patients with chronic pain. The CME is still available online.

97. Teva's sales representatives set up hundreds of speaker programs for doctors, including many non-oncologists, which promoted Actiq and Fentora for the treatment of non-cancer pain. Upon information and belief, these programs were attended by Lake County prescribers.

98. In December 2011, Teva widely disseminated a journal supplement entitled "Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)" to Anesthesiology News, Clinical Oncology News, and Pain Medicine News—three publications that are sent to thousands of anesthesiologists and other medical professionals nationally, including, upon information and belief, in Lake County. The Special Report openly promotes Fentora for "multiple causes of pain,"and not just cancer pain.

99. Teva's deceptive marketing gave doctors and patients the false impression that Actiq and Fentora were not only safe and effective for treating chronic pain, but also were approved by the FDA for such uses. Based on data publicly reported by Teva, of the 235 visits to prescribers in the County to market Fentora, only 10 were to oncologists. By contrast, anesthesiologists, family and internal medicine practitioners, and physical medicine and rehabilitation specialists received the most visits by Teva's sales representatives and, nationally, over 87% of spending.

100. On December 28, 2011, the FDA mandated a Risk Evaluation and Mitigation Strategy (REMS) for the class of products for which Teva's Actiq and Fentora belong, Transmucosal Immediate Release Fentanyl (TIRF). The TIRF REMS programs include mandatory patient and prescriber enrollment forms, as well as certification requirements for prescribers. The forms are not comprehensive and do not, for instance, disclose that addiction can develop when prescribed as directed, nor do they disclose that risks are greatest at higher doses—and patients must already be taking high doses of opioids to be prescribed Actiq and Fentora.

2. Overstating opioids' effect on patients' function and quality of life

101. Manufacturing Defendants also claimed—without evidence—that long-term opioid use would help patients resume their lives and jobs.

102. Lake County prescribers confirm that Purdue's sales representatives promoted the ability of opioids to improve patients' function and quality of life in detail in the County.

103. Manufacturing Defendants' materials that, upon information and belief, were distributed or made available in the County, reinforced this message. The 2011 American Pain Foundation publication *A Policymaker's Guide to Understanding Pain & Its Management*, falsely claimed that "multiple clinical studies have shown that opioids are effective in

improving" "daily function" and "[o]verall health-related quality of life for people with chronic pain." A series of medical journal advertisements for OxyContin in 2012 presented "Pain Vignettes"—case studies featuring patients with pain conditions persisting over several months—that implied functional improvement. For example, one advertisement described a "writer with osteoarthritis of the hands" and implied that OxyContin would help him work more effectively. Similarly, since at least May of 2011, Endo has distributed and made available on its website, opana.com, a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like construction worker and chef, misleadingly implying that the drug would provide long-term pain-relief and functional improvement.

104. Additional illustrative examples are described below:

a. Janssen sponsored and edited a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009),which states as "a fact" that "opioids may make it *easier* for people to live normally." The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs and states that "[u]sed properly, opioid medications can make it possible for people with chronic pain to 'return to normal.'"

b. *Responsible Opioid Prescribing* (2007), sponsored and distributed by Teva, Endo and Purdue, taught that relief of pain by opioids, by itself, improved patients' function. The book remains for sale online.

c. Purdue and Teva sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids "give [pain patients] a quality of life we deserve." The guide was available online until APF shut its doors in May 2012.

d. Endo's NIPC website *painknowledge.com* claimed in 2009 that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC's intent to make claims of functional improvement, and Endo closely tracked visits to the site.

e. Endo was the sole sponsor, through NIPC, of a series of CMEs titled *Persistent Pain in the Older Patient*, which claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning." The CME was disseminated via webcast.

105. Likewise, Manufacturing Defendants' claims that long-term use of opioids improves patient function and quality of life are unsupported by clinical evidence. As noted above, there are no controlled studies of the use of opioids beyond 16 weeks, and there is no evidence that opioids improve patients' pain and function long-term. On the contrary, the available evidence indicates opioids are not effective to treat chronic pain, and may worsen patients' health and pain. Increasing the duration of opioid use is strongly associated with an increasing prevalence of mental health conditions (depression, anxiety, post-traumatic stress disorder, and substance abuse), increased psychological distress, and greater health care utilization.

106. As one pain specialist observed, "opioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally."[21] Studies of patients with lower back pain and migraine headaches, for example, have consistently shown that patients experienced deteriorating function over time, as measured by ability to return to work, physical activity, pain relief, rates of depression, and subjective quality-of-life measures. Analyses of workers' compensation claims have found that workers who take opioids are almost four times more likely to reach costs over $100,000, stemming from greater side effects and slower returns to work.

[21] Andrea Rubinstein, *Are We Making Pain Patients Worse?*, Sonoma Med. (Fall 2009), available at http://www.nbcms.org/about-us/sonoma-county-medical-association/magazine/sonoma-medicine-are-we-making-pain-patients-worse?

According to these studies, receiving an opioid for more than seven days also increased patients' risk of being on work disability one year later.

107. The FDA and other federal agencies have, for years, made clear the lack of evidence for claims that the use of opioids for chronic pain improves patients' function and quality of life.[22] The CDC Guideline concluded that "[w]hile benefits for pain relief, function and quality of life with long-term opioid use for chronic pain are uncertain, risks associated with long-term opioid use are clearer and significant."[23] According to the CDC, "for the vast majority of patients, the known, serious, and too-often-fatal risks far outweigh the unproven and transient benefits [of opioids for chronic pain]."[24]

3. Omitting or mischaracterizing adverse effects of opioids

108. In materials Manufacturing Defendants produced, sponsored, or controlled, these Defendants omitted known risks of chronic opioid therapy and emphasized or exaggerated risks of competing products so that prescribers and patients would be more likely to choose opioids and would favor opioids over other therapies such as over-the-counter acetaminophen or

[22] The FDA has warned other drug makers that claims of improved function and quality of life were misleading. *See,* Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), (rejecting claims that Actavis' opioid, Kadian, had an "overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."); Warning Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Brian A. Markison, Chairman, President and Chief Executive Officer, King Pharmaceuticals, Inc. (March 24, 2008), (finding the claim that "patients who are treated with [Avinza (morphine sulfate ER)] experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."). The FDA's warning letters were available to Defendants on the FDA website.

[23] *Id* at 18.

[24] Thomas R. Frieden and Debra Houry, New England Journal of Medicine, "Reducing the Risks of Relief—The CDC Opioid-Prescribing Guideline" at 1503 (Apr. 21, 2016).

nonsteroidal anti-inflammatory drugs (or NSAIDs, like ibuprofen). None of these claims were corroborated by scientific evidence.

109. In addition to failing to disclose in promotional materials the risks of addiction, abuse, overdose, and death, Manufacturing Defendants routinely ignored other risks, such as hyperalgesia, a "known serious risk associated with chronic opioid analgesic therapy,"[25] in which the patient becomes more sensitive to pain over time; hormonal dysfunction; decline in immune function; mental clouding, confusion, and dizziness; increased falls and fractures in the elderly; neonatal abstinence syndrome (when an infant exposed to opioids prenatally withdraws from the drugs after birth); and potentially fatal interactions with alcohol or benzodiazepines, which are used to treat post-traumatic stress disorder and anxiety (conditions that often accompany chronic pain symptoms).

110. Purdue and Teva sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids differ from NSAIDs in that they have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. The publication inaccurately attributes 10,000 to 20,000 deaths annually to NSAIDs (the actual figure is approximately 3,200—far fewer than from opioids).[26] This publication also warned that risks of NSAIDs increase if "taken for more than a period of months," with no corresponding warning about opioids.

111. Purdue and Endo also sponsored APF's *Exit Wounds* (2009), a book aimed at veterans. This book omits warnings of the potentially fatal risk of interactions between opioids

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[25] *See* n. 15, *supra*.

[26] The higher figure reflects deaths from all causes.

and benzodiazepines, a class of drug commonly prescribed to veterans with post-traumatic stress disorder. This book is available from Amazon.com and other retailers.

112. Purdue and Endo sponsored a CME program, *Overview of Management Options*, published by the American Medical Association in 2003, 2007, 2010, and 2013, and discussed further below. The CME was edited by Dr. Russell Portenoy, among others, and taught that NSAIDs and other drugs, but not opioids, are unsafe at high doses.

113. Manufacturing Defendants frequently contrasted the lack of a ceiling dosage for opioids with the risks of NSAIDs. These Defendants deceptively describe the risks from NSAIDs while failing to disclose the risks from opioids. (*See e.g.*, *Case Challenges in Pain Management: Opioid Therapy for Chronic Pain* (Endo) [describing massive gastrointestinal bleeds from long-term use of NSAIDs and recommending opioids]; *Finding Relief: Pain Management for Older Adults* (Janssen) [NSAIDs caused kidney or liver damage and increased risk of heart attack and stroke, versus opioids, which cause temporary "upset stomach or sleepiness" and constipation].)

114. These omissions are significant and material to patients and prescribers. A Cochrane Collaboration review of evidence relating to the use of opioids for chronic pain found that 22% of patients in opioid trials dropped out before the study began because of the "intolerable effects" of opioids.[27]

115. Again, Manufacturing Defendants' misrepresentations were effective. A study of 7.8 million doctor visits nationwide between 2000 and 2010 found that opioid prescriptions increased from 11.3% to 19.6% of visits while NSAID and acetaminophen prescriptions fell

[27] Meredith Noble M, *et al.*, *Long- Term Opioid Management for Chronic Noncancer Pain (Review)*, Cochrane Database of Systematic Reviews, Issue 1, 11 (2010).

from 38% to 29%. The CDC reports that the quantity of opioids dispensed per capita tripled from 1999 to 2015.

D. MANUFACTURING DEFENDANTS CONTINUED TO TELL DOCTORS THAT OPIOIDS COULD BE TAKEN IN EVER-HIGHER DOSES WITHOUT DISCLOSING THEIR GREATER RISKS.

116. Manufacturing Defendants falsely claimed to prescribers and consumers that opioids could be taken in ever-increasing strengths to obtain pain relief, without disclosing that higher doses increased the risk of addiction and overdose. This was particularly important because patients on opioids for more than a brief period develop tolerance, requiring increasingly high doses to achieve pain relief. These Defendants needed to generate a comfort level among doctors to ensure the doctors maintained patients on the drugs even at the high doses that became necessary. Further, as described in more detail in Section E, Purdue encouraged doctors to prescribe higher doses, rather than prescribe OxyContin more frequently than twice-a-day—despite knowing that OxyContin frequently did not provide 12 hours of relief. Manufacturing Defendants' sales representatives' failed to disclose to prescribers in Lake County the increased risk at higher doses. And, based on data from the County's employee benefits plan, the average dose of Nucynta, Nucynta ER, OxyContin, and Opana ER all exceeded 90 MED, the highest dose recommended by the CDC.

117. Purdue-sponsored publications and CMEs available online also misleadingly suggested that higher opioid doses carried no added risk.

118. Through at least June 2015, Purdue's *In the Face of Pain* website promoted the notion that if a patient's doctor did not prescribe a sufficient dose of opioids, the patient should see different doctors until finding a doctor who would.

119. *A Policymaker's Guide,* the 2011 publication on which, upon information and belief, Purdue collaborated with APF, taught that dose escalations are "sometimes necessary," but it did not disclose the risks from high dose opioids. This publication is still available online.

120. The Purdue-sponsored CME, *Overview of Management Options*, discussed above, again instructed physicians that NSAIDs (like ibuprofen) are unsafe at high doses (because of risks to patients' kidneys), but it did not disclose risks from opioids at high doses.

121. Endo sponsored a website, painknowledge.com, which claimed in 2009 that opioid dosages may be increased until "you are on the right dose of medication for your pain."

122. Endo distributed a pamphlet edited by Dr. Russell Portenoy entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*, which appeared on Endo's website. In Q&A format, it asked "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased. . . . You won't 'run out' of pain relief."

123. Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which was distributed by its sales force. This guide listed dosage limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased opioid dosages. This guide is still available online.

124. These claims conflict with the scientific evidence. Patients receiving high doses of opioids (*e.g.*, doses greater than 100 mg morphine equivalent dose ("MED") per day) as part of long-term opioid therapy are three to nine times more likely to suffer overdose from opioid-related causes than those on low doses. As compared to available alternative pain remedies, scholars have suggested that tolerance to the respiratory depressive effects of opioids develops at a slower rate than tolerance to opioids' analgesic effects. Accordingly, the practice of

continuously escalating doses to match pain tolerance can, in fact, lead to overdose even where opioids are taken as recommended.

125. The CDC Guideline concludes that the "[b]enefits of high-dose opioids for chronic pain are not established" while "there is an increased risk for serious harms related to long-term opioid therapy that appears to be dose-dependent."[28] That is why the CDC advises doctors to "avoid increasing doses" above 90 mg MED.[29]

E. PURDUE MISLEADINGLY PROMOTED OXYCONTIN AS SUPPLYING 12 HOURS OF PAIN RELIEF WHEN PURDUE KNEW THAT, FOR MANY PATIENTS, IT DID NOT.

126. To convince prescribers and patients to use OxyContin, Purdue misleadingly promoted the drug as providing 12 continuous hours of pain relief with each dose. In reality, OxyContin does not last for 12 hours in many patients, a fact Purdue has known since the product's launch.

127. OxyContin has been FDA-approved for twice-daily—"Q12"—dosing frequency since its debut in 1996. Purdue sought that dosing frequency in order to maintain a competitive advantage over more frequently dosed opioids. Even so, Purdue has gone well beyond the label's instructions to take OxyContin every 12 hours by affirmatively claiming, in their general marketing and, upon information and belief, to prescribers in the County, that OxyContin lasts for 12 hours and as a key advantage of OxyContin, and by failing to disclose that OxyContin fails to provide 12 hours of pain relief to many patients. These misrepresentations, which Purdue

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[28] CDC Guideline at 19. The 2016 CDC Guideline reinforces earlier findings announced by the FDA. In 2013, the FDA acknowledged "that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events." For example, the FDA noted that studies "appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality."

[29] CDC Guideline at 16.

continues to make, are particularly dangerous because inadequate dosing helps fuel addiction, as explained below.

128. From the outset, Purdue leveraged 12-hour dosing to promote OxyContin as providing continuous, round-the-clock pain relief with the convenience of not having to wake to take a third or fourth pill. The 1996 press release for OxyContin touted 12-hour dosing as providing "smooth and sustained pain control all day and all night." But the FDA has never approved such a marketing claim. To the contrary, the FDA found in 2008, in response to a Citizen Petition by the Connecticut Attorney General, that a "substantial number" of chronic pain patients taking OxyContin experienced "end of dose failure"—*i.e.,* little or no pain relief at the end of the dosing period.

129. Moreover, Purdue itself long has known, dating to its development of OxyContin, that the drug wears off well short of 12 hours in many patients. In one early Purdue clinical trial, a third of patients dropped out because the treatment was ineffective. Researchers changed the rules to allow patients to take supplemental painkillers—"rescue medication"—in between OxyContin doses. In another study, most patients used rescue medication, and 95% resorted to it at least once. In other research conducted by Purdue, the drug wore off in under 6 hours in 25% of patients and in under 10 hours in more than 50%.

130. End-of-dose failure renders OxyContin even more dangerous because patients begin to experience withdrawal symptoms, followed by a euphoric rush with their next dose—a cycle that fuels a craving for OxyContin. For this reason, Dr. Theodore Cicero, a neuropharmacologist at the Washington University School of Medicine in St. Louis, has called

OxyContin's 12-hour dosing "the perfect recipe for addiction."[30] Many patients will exacerbate this cycle by taking their next dose ahead of schedule or resorting to a rescue dose of another opioid, increasing the overall amount of opioids they are taking.

131. Purdue has remained committed to 12-hour dosing because it is key to OxyContin's market dominance and comparatively high price; without this advantage, the drug had little to offer over less expensive, short-acting opioids. In a 2004 letter to the FDA, Purdue acknowledged that it had not pursued approval to allow more frequent dosing in the label (*e.g.*, every 8 hours) because 12-hour dosing was "a significant competitive advantage."

132. While Purdue's commitment to marketing opioids as a 12-hour drug made it more addictive, Purdue falsely promoted OxyContin as providing "steady state" relief and less likely than other opioids to create a cycle of crash and cravings that fueled addiction and abuse. Purdue sales representatives described OxyContin to County prescribers as providing a steady, even stream of medicine, as longer lasting, or as 12-hour medicine. Purdue also marketed Hysingla ER in the County as better for chronic pain because it would not have the same highs and lows as other pills and presented less risk of diversion as patients would be taking fewer pills.

133. Promotion of 12-hour dosing, without disclosing its limitations, is misleading because it implies that the pain relief supplied by each dose lasts 12 hours. FDA approval of OxyContin for 12-hour dosing does not give Purdue license to misrepresent the duration of pain relief it provides to patients; moreover, Purdue had a responsibility to correct its label to reflect

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[30] Harriet Ryan, "'*You Want a Description of Hell?' OxyContin's 12-Hour Problem*," Los Angeles Times, May 5, 2016, available at http://www.latimes.com/projects/oxycontin-part1/.

appropriate dosing and to disclose to prescribers what it knew about OxyContin's actual duration, regardless of any marketing advantage.[31]

134. Purdue was also aware of some physicians' practice of prescribing OxyContin more frequently than 12 hours—a common occurrence. Purdue's promoted solution to this problem was to increase the dose, rather than the frequency, of prescriptions, even though higher dosing carries its own risks—including increased danger of addiction, overdose, and death. It means that patients will experience higher highs and lower lows, increasing their craving for their next pill. Nationwide, based on an analysis by the *Los Angeles Times*, more than 52% of patients taking OxyContin longer than three months are on doses greater than 60 milligrams per day—which converts to the 90 MED that the CDC Guideline urges prescribers to "avoid" or "carefully justify."[32] According to data from the County's employee benefits plan, the average daily dose of OxyContin exceeded 100 MED, above the highest dose of 90 MED recommended by the CDC.

F. PURDUE AND ENDO OVERSTATED THE EFFICACY OF ABUSE-DETERRENT OPIOID FORMULATIONS.

135. Rather than take the widespread abuse and addiction to opioids as reason to cease their untruthful marketing claims and efforts, Manufacturing Defendants Purdue and Endo seized them as a market opportunity. These companies oversold their abuse-deterrent formulations ("ADF") as a solution to opioid abuse and as a reason that doctors could continue to safely prescribe their opioids. Purdue's and Endo's false and misleading marketing of the benefits of its ADF opioids preserved and expanded their sales and enabled prescribers to discount evidence

[31] For example, Kadian, an opioid manufactured by Allergan, was designed to be taken once a day, but the label acknowledges and advises dosing of up to every 12 hours for certain patients.

[32] CDC Guideline at 16.

of opioid addiction and abuse and attribute it to other, less safe opioids—thereby prolonging the opioid epidemic in Lake County.

1. Purdue's Deceptive Marketing of Reformulated OxyContin and Hysingla ER.

136. Reformulated ADF OxyContin was approved by the FDA in April 2010. It was not until 2013 that the FDA, in response to a Citizen Petition filed by Purdue, permitted reference to the abuse-deterrent properties in its label. However, the FDA made clear that abuse-deterrent properties do not stop tampering but only make it harder to modify the pills. ADF pills can still be snorted and injected if tampered with, and these pills are still sought after by abusers because of their high likability when snorted. Further, ADF properties do not reduce oral abuse—the most common form of abuse—in any way. When Hysingla ER (extended-release hydrocodone) launched in 2014, the product included similar abuse-deterrent properties and limitations.

137. It is unlikely a coincidence that reformulated OxyContin was introduced shortly before generic versions of OxyContin were to become available, threatening to erode Purdue's market share and the price it could charge. Through a Citizen Petition, Purdue was able to secure a determination by the FDA in April 2013 that original OxyContin should be removed from the market as unsafe (lacking abuse-deterrent properties), and thus non-ADF generic copies could not be sold. As a result, Purdue extended its branded exclusivity for OxyContin until the patent protection on the abuse-deterrent coating expires.

138. Purdue nonetheless touted its introduction of ADF opioids as evidence of its good corporate citizenship and commitment to address the opioid crisis. Touting the benefits of ADF opioids, Purdue's website asserts, for instance: "we are acutely aware of the public health risks

these powerful medications create . . . That's why we work with health experts, law enforcement, and government agencies on efforts to reduce the risks of opioid abuse and misuse . . . ."[33]

139. Ironically, Purdue sales representatives also regularly overstated and misstated the evidence for and impact of the abuse-deterrent features of these opioids. Specifically, Purdue detailers:

a. claimed that Purdue's ADF opioids prevent tampering and that its ADFs could not be crushed or snorted;

b. claimed that Purdue's ADF opioids reduce opioid abuse and diversion;

c. failed to disclose that Purdue's ADF opioids do not impact oral abuse or misuse or can cause patients to turn to heroin, with greater risks of injury.

140. Interviews with Lake County doctors confirm that abuse-deterrence was a central marketing message of Purdue's sales representatives, who encouraged ADF opioids to prevent abuse. In detailing visits in the County, Purdue also claimed that Hysingla ER and OxyContin would be hard to divert or abuse, could not be crushed, and that alternatives were inferior to ADF opioids because of the possibility of abuse, while at the same time failing to disclose that the abuse-deterrent features do not affect oral abuse and can be readily defeated. Purdue also falsely claimed that addicts would be would not get a high from its abuse-deterrent opioids. These misrepresentations and omissions are misleading and contrary to Purdue's labels.

141. Purdue knew or should have known that "reformulated OxyContin is not better at tamper resistance than the original OxyContin"[34] and is still regularly tampered with and abused.

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[33] Purdue website, *Opioids With Abuse-Deterrent Properties*, available at http://www.purduepharma.com/healthcare-professionals/responsible-use-of-opioids/opioids-with-abuse-deterrentproperties/.

[34] *In re OxyContin*, 1:04-md-01603-SHS, Docket No. 613, Oct. 7, 2013 hr'g, Testimony

Websites and message boards used by drug abusers, such as bluelight.org and reddit.com, report a variety of ways to tamper with OxyContin and Hysingla ER, including through grinding, microwaving then freezing, or drinking soda or fruit juice in which a tablet is dissolved. A publicly available Citizen Petition submitted to the FDA in 2016 by a drug manufacturing firm challenged Purdue's abuse-deterrent labeling based on the firm's ability to easily prepare so-called abuse deterrent OxyContin to be snorted or injected. Opioid addicts in Lake County also continued to crush, snort, and inject abuse-deterrent formulations of their drugs.

142. *One-third* of the patients in a 2015 study defeated the ADF mechanism and were able to continue inhaling or injecting the drug. To the extent that the abuse of Purdue's ADF opioids was reduced, those addicts simply shifted to other drugs such as heroin. In fact, law enforcement officials in Lake County noted an increase in heroin use after ADF opioids were introduced onto the market, and note that the vast majority of heroin users started with prescription opioids.

143. A 2013 article presented by Purdue employees based on review of data from poison control centers, concluded that ADF OxyContin can reduce abuse, it but ignored important negative findings. The study revealed that abuse merely shifted to other drugs and that, when the actual incidence of harmful exposures was calculated, there were *more* harmful exposures to opioids (including heroin) after the reformulation of OxyContin. In short, the article deceptively emphasized the advantages and ignored the disadvantages of ADF OxyContin.

144. The CDC Guideline confirms that "*[n]o* studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," noting

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of Dr. Mohan Rao, 1615:7-10.

that the technologies "do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by non-oral routes."[35] Tom Frieden, the Director of the CDC, reported that his staff could not find "any evidence showing the updated opioids [ADF opioids] actually reduce rates of addiction, overdoses, or death."[36]

145. In 2015, claiming a need to further assess its data, Purdue abruptly withdrew a supplemental new drug application related to reformulated OxyContin one day before FDA staff was to release its assessment of the application. The staff review preceded an FDA advisory committee meeting related to new studies by Purdue "evaluating the misuse and/or abuse of reformulated OxyContin" and whether those studies "have demonstrated that the reformulated product has a meaningful impact on abuse."[37] Upon information and belief, Purdue never presented the data to the FDA because the data would not have supported claims that OxyContin's ADF properties reduced abuse or misuse.

146. Despite the qualifying language in Purdue's label and its own evidence—and lack of evidence—regarding the impact of its ADF opioids in reducing abuse, Dr. J. David Haddox, the Vice President of Health Policy for Purdue, falsely claimed in 2016 that the evidence does not show that Purdue's ADF opioids are being abused in large numbers.

2. Endo's Deceptive Marketing of Reformulated Opana ER.

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[35] CDC Guideline at 22. (emphasis added).

[36] Matthew Perrone, *Drugmakers Push Profitable, but Unproven, Opioid Solution*, Assoc. Press (Jan. 2, 2017), available at http://www.detroitnews.com/story/news/nation/2017/01/02/painkillers-drugmakers-addictive/96095558.

[37] Meeting Notice, Joint Meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee; Notice of Meeting, May 25, 2015, 80 FR 30686.

147. In a strategy that closely resembled Purdue's, Endo, as the expiration of its patent exclusivity for Opana ER neared, and aware that it needed to be able to compete with other opioids, like OxyContin, that were being introduced as ADFs, also made abuse-deterrence a key to its marketing strategy.

148. In December 2011, Endo obtained approval for a new formulation of Opana ER that added a hard coating that the company claimed made it crush-resistant. Even prior to its approval, the FDA advised Endo in January 2011 that it could not market new Opana ER as abuse-deterrent. The FDA found that such promotional claims "may provide a false sense of security since the product may be chewed and ground for subsequent abuse."[38] In other words, Opana ER was still crushable. Indeed, in its approval package, Endo admitted that "[i]t has not been established that this new formulation of Opana ER is less subject to misuse, abuse, diversion, overdose, or addiction."

149. Nonetheless, in August of 2012, Endo submitted a confidential Citizen Petition asking the FDA for permission to change its label to indicate that Opana ER was abuse-resistant, both in that it was less able to be crushed and snorted, and that it was resistant to "aqueous extraction," or injection by syringe. Borrowing a page from Purdue's playbook, Endo announced it would withdraw original Opana ER from the market and sought a determination that its decision was made for safety reasons (its lack of abuse deterrence). That would prevent generic copies of original Opana ER from competitors, such as Impax Laboratories ("Impax"), which had sought approval to sell a generic version of the drug.

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[38] Attorney General of the State of New York, *In the Matter of Purdue Pharma L.P.*, Assurance No.: 15-151, Assurance of Discontinuance Under Executive Law Section 63, Subdivision 15 at 5.

150. Endo then sued the FDA, seeking to force expedited consideration of its Citizen Petition. The court filings confirmed its Endo's true motives: in a declaration submitted with its lawsuit, Endo's chief operating officer indicated that a generic version of Opana ER would decrease the company's revenue by up to $135 million per year. Endo also claimed that if the FDA did not block generic competition, $125 million, which Endo spent on developing the reformulated drug to "promote the public welfare" would be lost.[39] The FDA responded that: "Endo's true interest in expedited FDA consideration stems from business concerns rather than protection of the public health."[40]

151. Despite Endo's purported concern with public safety, not only did Endo continue to distribute original Opana ER for nine months after the reformulated version became available, it declined to recall original Opana ER despite its dangers. In fact, Endo also claimed in September 2012 to be "proud" that "almost all remaining inventory" of the original Opana ER had "been utilized."[41]

152. In its Citizen Petition, Endo asserted that redesigned Opana ER had "safety advantages." However, in rejecting the Petition in a 2013 decision, the FDA found that "study data show that the reformulated version's extended-release features can be compromised when subjected to ... cutting, grinding, or chewing." The FDA also determined that "reformulated

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[39] Plaintiff's Opposition to Defendants' and Intervenor's Motions to Dismiss and Plaintiff's Reply in Support of Motion for Preliminary Injunction ("Endo Br."), *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*., No. 1:12-cv-01936, Doc. 23 at 20 (D.D.C. Dec.14, 2012).

[40] Defendants' Response to the Court's November 30, 2012 Order, *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*., No. 1:12-cv-01936, Doc. 9 at 6 (D.D.C. Dec. 3, 2012).

[41] *Id.*; Endo News Release, Sept. 6, 2012 (Ex. L to Rurka Decl.) *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*., No. 1:12-cv-01936 ,Doc. 18-4(D.D.C. Dec. 9, 2012).

Opana ER" could also be "readily prepared for injections and more easily injected[.]" In fact, the FDA warned that preliminary data—including in Endo's own studies—suggested that a higher percentage of reformulated Opana ER abuse is via injection than was the case with the original formulation.

153. Over time, evidence continued to mount that injection was becoming the preferred means of abusing Opana ER, making Opana ER *less safe* than the original formulation. Injection carries risks of HIV, Hepatitis C, and, in reformulated Opana ER's specific case, the blood-clotting disorder thrombotic thrombocytopenic purpura (TTP), which can cause kidney failure.[42] In 2009, only 3% of Opana ER abuse was by intravenous means. Since the reformulation, injection of Opana ER increased by more than 500%.

154. Nevertheless, Endo continued to market the drug as tamper-resistant and abuse-deterrent. Indeed, detailers for Endo informed doctors, including, upon information and belief, doctors in Lake County, that Opana ER was abuse-deterrent, could not be tampered with, and was safe. In addition, upon information and belief, Endo sales representatives did not disclose to doctors in the County evidence that Opana was easier to abuse intravenously.

155. Likewise, a review of nationally-collected surveys of prescribers regarding their "take-aways" from pharmaceutical detailing confirms that prescribers remember being told Opana ER was tamper resistant, even after the May 2013 denial of Endo's Citizen Petition.

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[42] The CDC does not know why the redesigned Opana ER causes TTP, but it notes it did not appear in other prescription opioids prepared for injection. "Thrombotic Thrombocytopenic Purpura (TTP)–Like Illness Associated with Intravenous Opana ER Abuse — Tennessee, 2012," *Morbidity and Mortality Weekly Report* (Jan. 11, 2013). The CDC suggested it could be linked to inactive ingredients that make the product more difficult to crush or grind. No reports of Opana ER and TTP occurred prior to the reformulation.

Endo also tracked messages that doctors took from its in-person marketing. Among the advantages of Opana ER, according to participating doctors, was its "low abuse potential."

156. In its written materials, Endo marketed Opana ER as having been ***designed*** to be crush resistant, knowing that this would (falsely) imply that Opana ER actually ***was*** crush resistant and that this crush-resistant quality would make Opana ER less likely to be abused. For example, a June 14, 2012 Endo press release announced "the completion of the company's transition of its OPANA ER franchise to the new formulation designed to be crush resistant."[43] The press release further stated that: "We firmly believe that the new formulation of OPANA ER, coupled with our long-term commitment to awareness and education around appropriate use of opioids will benefit patients, physicians and payers."[44] In September 2012, another Endo press release stressed that reformulated Opana ER employed "INTAC Technology" and continued to describe the drug as "designed to be crush-resistant."[45]

157. Similarly, journal advertisements that appeared in April 2013 stated Opana ER was "designed to be crush resistant."

158. In a 2016 settlement with Endo, the New York Attorney General found that statements that Opana ER was "designed to be, or is crush resistant" were false and misleading because there was no difference in the ability to extract the narcotic from Opana ER. The New York Attorney General also found that Endo failed to disclose its own knowledge of the

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[43] Ex. E to Rurka Decl., *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*, No. 12-v-1936, Doc. 18-2 at 1 (D.D.C. Dec. 9, 2012).

[44] *Id.*

[45] Endo News Release, Sept. 6, 2012 (Ex. L to Rurka Decl) *Endo Pharmaceuticals Inc. v. U.S. Food and Drug Administration, et al.*., No. 1:12-cv-01936,Doc. 18-4 (D.D.C. Dec. 9, 2012).

crushability of redesigned Opana ER in its marketing to insurers and pharmacy benefit managers, which also would have impacted the availability of Opana ER in the County.

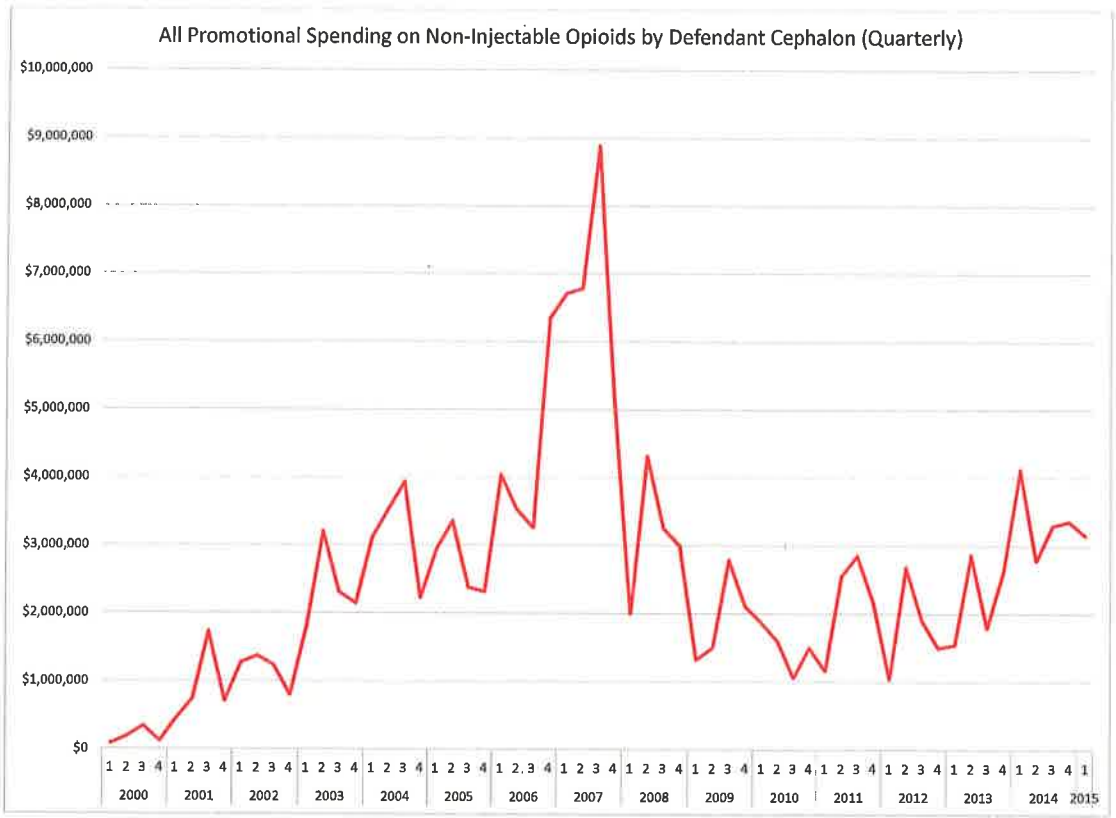
G. BY INCREASING OPIOID PRESCRIPTIONS AND USE, DEFENDANTS COLLECTIVELY FUELED THE OPIOID EPIDEMIC AND SIGNIFICANTLY HARMED LAKE COUNTY AND ITS RESIDENTS.

159. Defendants' misrepresentations prompted Lake County health care providers to prescribe, patients to take, and payors (including Lake County) to cover opioids for the treatment of chronic pain. Defendants overcame barriers to widespread prescribing of opioids for chronic pain with deceptive messages about the risks and benefits of long-term opioid use. The overprescribing and overuse of opioids in Lake County as a result of Defendants' wrongful conduct have devastated the County and its residents.

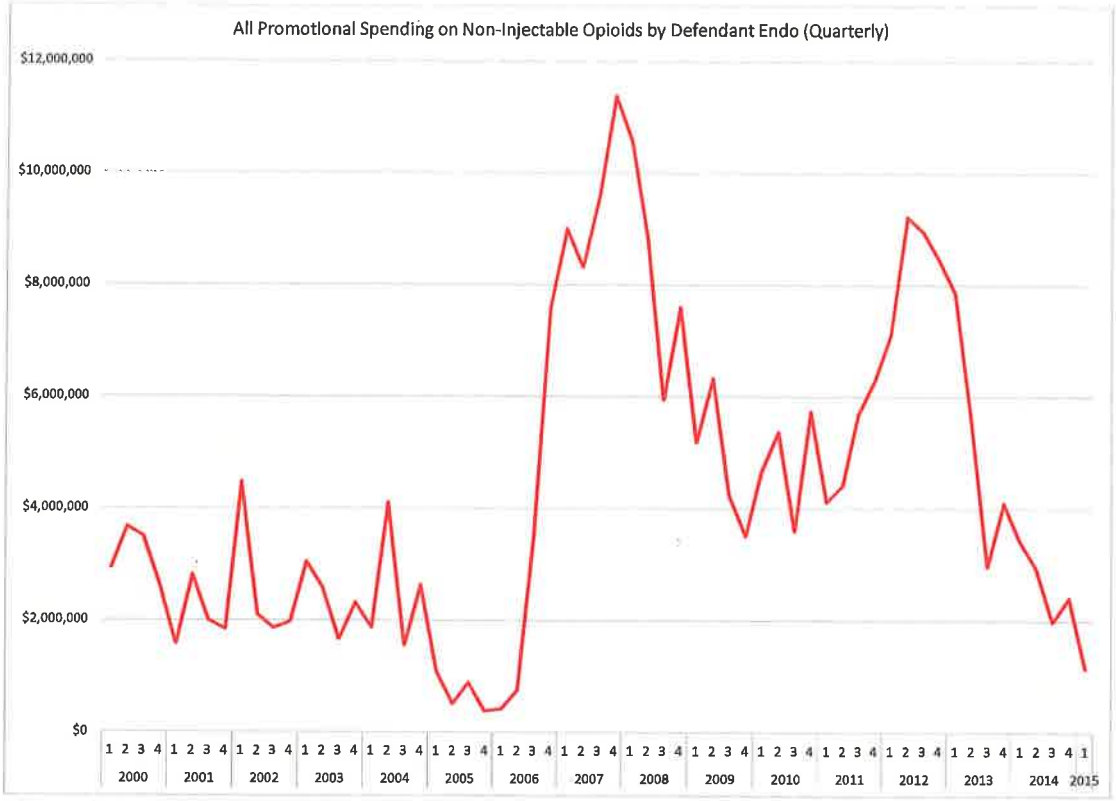
160. Defendants' deceptive promotion substantially contributed to an explosion in the use of opioids across the country and in Lake County. Approximately 20% of the population between the ages of 30 and 44, and nearly 30% of the population over 45, have used opioids. Opioids are now the most common treatment for chronic pain, and 20% of office visits now include the prescription of an opioid.

161. Manufacturing Defendants devoted and continue to devote massive resources to direct sales contacts with doctors. In 2014 alone, Manufacturing Defendants spent $166 million on detailing branded opioids to doctors. This amount is twice as much as Manufacturing Defendants spent on detailing in 2000. The amount includes $108 million spent by Purdue, $34 million by Janssen, $13 million by Teva, and $10 million by Endo.

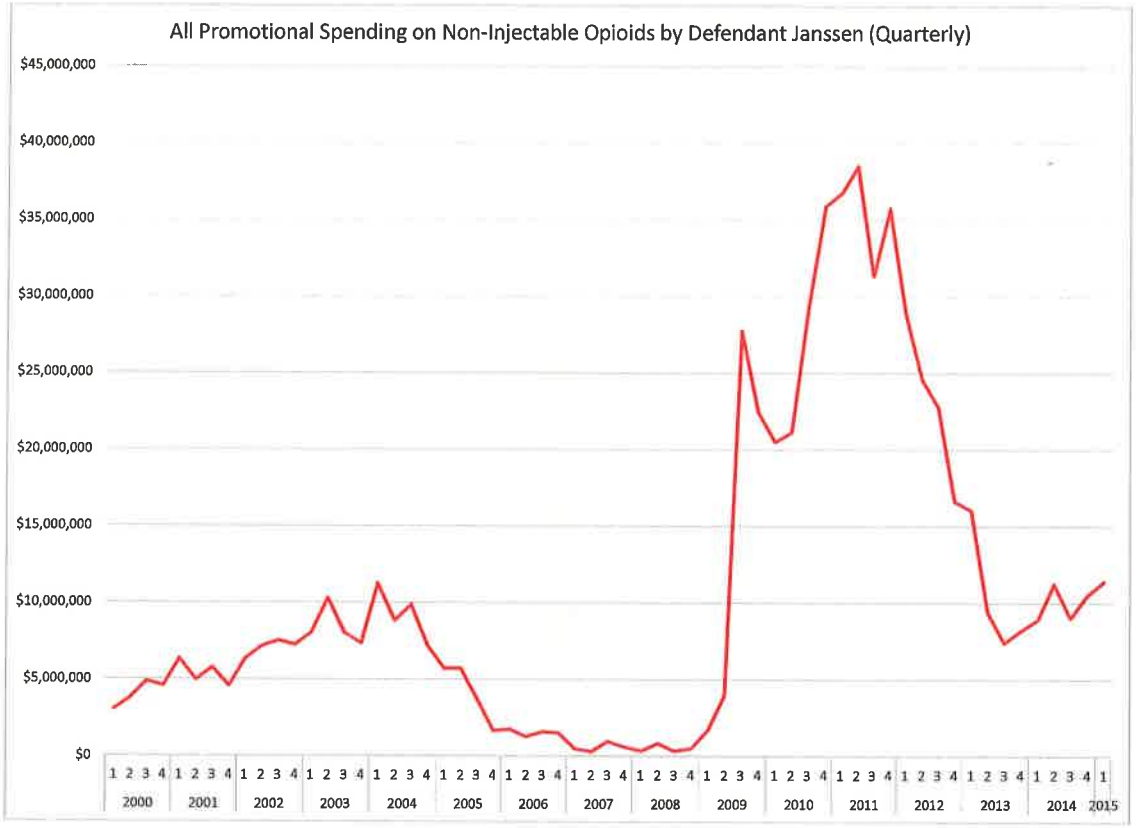
162. Cephalon's quarterly spending steadily climbed from below $1 million in 2000 to more than $3 million in 2014 (and more than $13 million for the year), with a peak, coinciding with the launch of Fentora, of nearly $9 million for one quarter of 2007 (and more than $27 million for the year), as shown below:



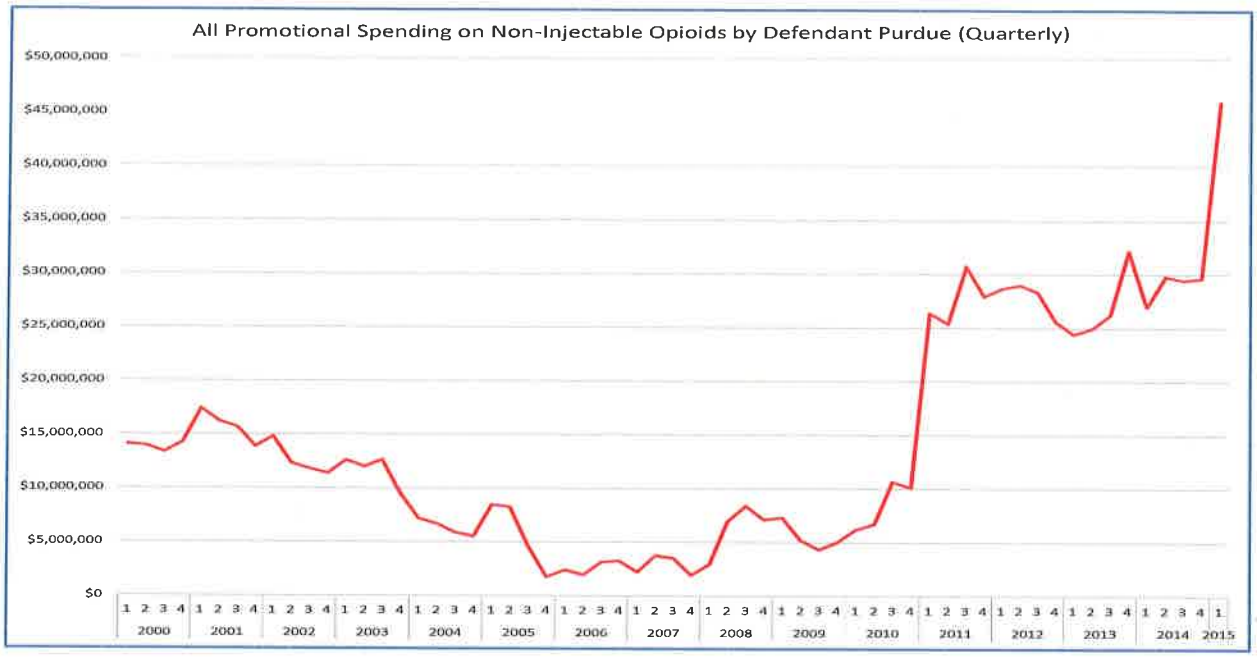
163. Endo's quarterly spending went from the $2 million to $4 million range in 2000-2004 to more than $10 million following the launch of Opana ER in mid-2006 (and more than $38 million for the year in 2007) and more than $8 million coinciding with the launch of a reformulated version in 2012 (and nearly $34 million for the year):



164. Janssen's quarterly spending dramatically rose from less than $5 million in 2000 to more than $30 million in 2011, coinciding with the launch of Nucynta ER (with yearly spending at $142 million for 2011), as shown below:



165. Purdue's quarterly spending notably decreased from 2000 to 2007, as Purdue came under investigation by the Department of Justice, but then spiked to above $25 million in 2011 (for a total of $110 million that year), and continues to rise, as shown below:



166. Each of Manufacturing Defendants' drugs and/or their generic equivalents have been marketed and prescribed in the County.

167. Each of Manufacturing Defendants' drugs and/or their generic equivalents have been marketed and prescribed in the County.

168. Defendants' detailing to doctors is effective. Numerous studies indicate that marketing impacts prescribing habits, with face-to-face detailing having the greatest influence. Indeed, virtually all of the top prescribers of opioids paid for by the County through its health benefits program received multiple detailing visits from Defendants sales representatives. One of these doctors alone received 118 sales visits from Defendants in the last four years.

169. The sharp increase in opioid use resulting from Defendants' conduct has led directly to a dramatic increase in opioid abuse, addiction, overdose, and death throughout the United States, including in the County. Representing the NIH's National Institute of Drug Abuse in hearings before the Senate Caucus on International Narcotics Control in May 2014, Dr. Nora Volkow explained that "aggressive marketing by pharmaceutical companies" is "likely to have contributed to the severity of the current prescription drug abuse problem."[46]

170. In August 2016, then U.S. Surgeon General Vivek Murthy published an open letter to physicians nationwide, enlisting their help in combating this "urgent health crisis" and linking that crisis to deceptive marketing. He wrote that the push to aggressively treat pain, and the "devastating" results that followed, had "coincided with heavy marketing to doctors . . . . [m]any of [whom] were even taught—incorrectly—that opioids are not addictive when prescribed for legitimate pain."[47]

171. Scientific evidence demonstrates a close link between opioid prescriptions and opioid abuse. For example, a 2007 study found "a very strong correlation between therapeutic exposure to opioid analgesics, as measured by prescriptions filled, and their abuse."[48]

172. There is a "parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and

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[46] "America's Addiction to Opioids: Heroin and Prescription Drug Abuse," *Senate Caucus on Int'l Narcotics Control*, hr'g, Testimony of Dr. Nora Volkow (May 14, 2014) available at http://www.drugcaucus.senate.gov/sites/default/files/Volkow%20Testimony.pdf.

[47] *See* n.2, *supra.*

[48] Theodore J Cicero *et al.*, *Relationship Between Therapeutic Use and Abuse* of *Opioid Analgesics in Rural, Suburban, and Urban* Locations in the United States, 16.8 Pharmacoepidemiology and Drug Safety, 827-40 (2007).

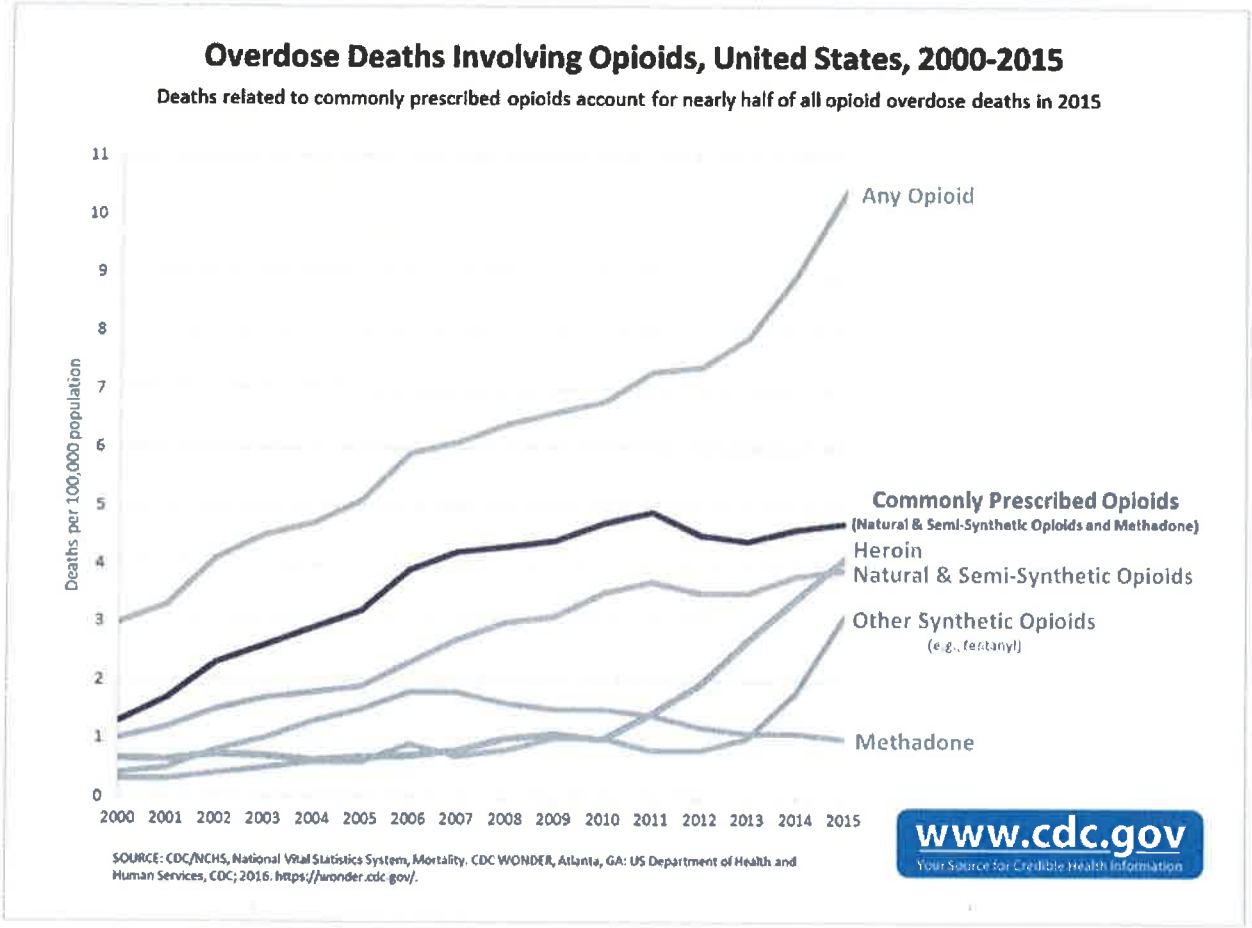
associated adverse outcomes."[49] The opioid epidemic is "directly related to the increasingly widespread misuse of powerful opioid pain medications."[50]

173. In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses." Patients receiving opioid prescriptions for chronic pain account for the majority of overdoses. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."[51] In the meantime, opioid overdoses continue to rise, as demonstrated by this chart:

[49] Dart, MD, *et al.*, *Trends in Opioid Analgesic Abuse and Mortality in the United States*, New Engl. J. Med., 372:241-248 (Jan. 15, 2015).

[50] Califf, MD, *et al.*, *A Proactive Response to Prescription Opioid Abuse,* New Engl. J. Med. (Apr. 14, 2016).

[51] CDC, January 1, 2016 Morbidity and Mortality Weekly Report; Rudd, Rose A., *et al.* "Increases in drug and opioid overdose deaths—United States, 2000–2014." American Journal of Transplantation 16.4 (2016): 1323-1327.



174. Lake County has suffered five times as many opioid overdose deaths in the last ten years—roughly 532—than in the nine years before that (and more opioid deaths in 2016 and 2017 alone than between 1999 and 2007).

175. The transition from prescription opioids to heroin (and, most recently, heroin plus synthetic fentanyl, which increases the highs from heroin) has made the epidemic in Lake County even more deadly. Individuals addicted to prescription opioids often transition to heroin due to its lower cost, ready availability, and similar high. The County had its first heroin death in 2004. Five years ago, heroin was scarce on the streets; now, according to law enforcement, it can be found everywhere in the County. Addiction treatment centers in Lake County report that the majority of their patients who abuse heroin migrated from prescription opioids, typically when doctors cut off their prescriptions.

176. Based on national data, people who are addicted to prescription opioid painkillers are 40 times more likely to be addicted to heroin. The CDC identified addiction to prescription pain medication as the strongest risk factor for heroin addiction. Roughly 80% of heroin users previously used prescription opioids. In 2016, over half of Illinois police chief and sheriffs surveyed identified heroin as the greatest drug threat in the state, and reported grapping with an increase in heroin distribution, transportation, and demand.

177. Overdose deaths are only one consequence of the opioid epidemic. Opioid addiction and misuse also result in an increase in emergency room visits, emergency responses, and emergency medical technicians' administration of Narcan or naloxone, the antidote to opioid overdose. The number of hospitalizations related to the abuse of opioids in Lake County increased from 728 in 2009 to 993 in 2014. There also has been an increase in the incidence of Hepatitis C and HIV among patients treated by the County for opioid addiction. The increase in Hepatitis C, in particular, according to the CDC, is directly tied to intravenous injection of opioids.

178. Even infants have not been immune to the impact of opioid abuse. There has been a dramatic rise in the number of infants who are born addicted to opioids due to prenatal exposure and suffer from neonatal abstinence syndrome ("NAS," also known as neonatal opioid withdrawal syndrome, or "NOWS"). These infants painfully withdraw from the drug once they are born, cry nonstop from the pain and stress of withdrawal, experience convulsions or tremors, have difficulty sleeping and feeding, and suffer from diarrhea, vomiting, and low weight gain, among other serious symptoms. The long-term developmental effects are still unknown, though research in other states has indicated that these children are likely to suffer from continued,

serious neurologic and cognitive impacts, including hyperactivity, attention deficit disorder, lack of impulse control, and a higher risk of future addiction.

179. In 2015, 373 infants were born in Illinois with NAS, reflecting a 62% increase in the Collar counties, including Lake County. The median hospitalization charges for infants without NAS were approximately $4,200, compared to approximately $46,200 for infants with NAS; and the cost to care for infants born with NAS statewide were $22 million higher than what would have been expected if they had been born without NAS.

180. Rising opioid use and abuse have negative social and economic consequences far beyond even these profound impacts on public health. According to a recent analysis by a Princeton University economist, approximately one out of every three working age men who are not in the labor force take daily prescription pain medication. The same research finds that opioid prescribing alone accounts for 20% of the overall decline in the labor force participation for this group from 2014-16, and 25% of the decline in labor force participation among women. Yet many of those taking painkillers still said they experienced pain daily.

181. Contrary to Defendants' misrepresentations, most of the illicit use originates from *prescribed* opioids. It has been estimated that 60% of the opioids that are abused come, directly or indirectly, through physicians' prescriptions. In 2011, 71% of people who abused prescription opioids got them through friends or relatives, not from drug dealers or the internet. (While not limited to opioids, the County's collection of 10,928 pounds of medications in 2016 provides one gauge of the volume of overprescribed opioids in the County available for misuse).

182. As a result of the impacts described above, and others, the County has incurred substantial expense to address the epidemic created by Defendants' misconduct.

183. The County has spent over $331,000 to cover a total of 9,830 claims for opioids through the County's employee health plan. Forty-two percent of that spending was for Purdue drugs (which represented 73% of the County's spending on branded opioids). *Roughly 95% of the County's spending for opioids was for chronic opioid therapy lasting three months or longer.*

184. The County has spent significant funds for costs associated with increased drug crimes, including costs for prosecutors, jail, and probation. Roughly 8% of individuals under probation supervision have an opioid addition, and 80% of probationers who receive residential treatment have an opioid addiction Net costs to the County for probation services, its specialty drug and veterans courts, and addiction treatment related to opioids was at least $429,000 in 2016 alone (not including costs like drug testing). This also excludes the increased costs from non-drug offenses, such as burglary, elder abuse, or domestic violence, that relate to opioid use.

185. Opioids are the most damaging drug to have hit the Lake County—the most addictive and most destructive in the drive they create for more drugs, whatever the cost or consequence. Law enforcement officials are pulled off other duties to respond to overdoses, and have had to grapple with increased crimes related to opioids, including armed robberies of pharmacies and burglaries across the County. No corner of the County has escaped the reach of opioids. A study of the estimated cost of crime related to drug use in Lake County placed the costs of property offenses at $4.2 million (a dramatic 11,045 offenses) in 2014 alone and $7.2 million for violent offenses, including 13 homicides, 599 aggravated assaults, and 145 rapes (1,032 offenses).

186. Opioids also have imposed significant costs on the County's jail. The number of opioid-dependent inmates have increased from 469 in 2015 to 764 in 2016, and is expected to exceed that number in 2017. These inmates must be closely supervised through often intense

withdrawal; an increase in inmates' suicide attempts appears related to their withdrawal from opioids. Opioid-addicted inmates are provided medication-assisted treatment and now receive addition treatment through the Health Department after their release. Providing treatment services to inmates costs the County roughly $3 million per year. The jail also provides Narcan to inmates upon discharge to help prevent future overdoses.

187. The Lake County Health Department's Crisis Center connects residents seeking treatment to addiction treatment services. The County itself provides residential and outpatient addiction treatment services for residents struggling with addiction, most of which stems from opioid addiction. In 2017, the County spent roughly $900,000 on substance abuse treatment programs, and projects it will spend over $1 million in 2018. In 2015, alcohol and drug abuse treatment in hospitals in the County cost roughly $11.5 million, much of which can be tied to opioid abuse.

188. These represent only some of the costs to the County from Defendants' deceptive—but very successful—marketing of opioids. It does not include the damages, in lives lost to, or transformed by addiction, that cannot be measured, compensated, or restored.

H. MANUFACTURING DEFENDANTS FRAUDULENTLY CONCEALED THEIR MISCONDUCT.

189. Manufacturing Defendants made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their marketing was false and misleading. The history of opioids, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes. The FDA and other regulators warned Manufacturing Defendants of this, and likewise, Purdue and Teva paid hundreds of millions of dollars to address similar misconduct that occurred before 2008. Manufacturing

Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths—all of which made clear the harms from long-term opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers. More recently, the FDA and CDC have issued pronouncements based on existing medical evidence that conclusively exposes the known falsity of these Defendants' misrepresentations.

190. Notwithstanding this knowledge, at all times relevant to this Complaint, Manufacturing Defendants took steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful and fraudulent conduct. Manufacturing Defendants disguised their own role in the deceptive marketing of chronic opioid therapy by funding and working through biased science, unbranded marketing, third party advocates, and professional associations. Purdue, Endo, Teva, and Janssen purposefully hid behind the assumed credibility of these sources and relied on them to establish the accuracy and integrity of Defendants' false and misleading messages about the risks and benefits of long-term opioid use for chronic pain. Purdue, Endo, Teva, and Janssen masked or never disclosed their role in shaping, editing, and approving the content of this information.

191. Manufacturing Defendants thus successfully concealed from the medical community, patients, and the County facts sufficient to arouse suspicion of the claims that the County now asserts. The County did not know of the existence or scope of these Defendants' fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence. Absent awareness of Manufacturing Defendants' deceptive conduct, the role of Front Group Defendants in their scheme also was unknown. Even publicly disclosed facts, such as the

financial support from Manufacturing Defendants, had little meaning without knowledge of the direction and control of the Manufacturing Defendants.

CAUSES OF ACTION

COUNT I

CONSUMER FRAUD—UNFAIR AND DECEPTIVE PRACTICES

VIOLATIONS OF 815 ILCS 505/1 *ET SEQ.*

PURSUANT TO 815 ILCS 505/7

AGAINST MANUFACTURING DEFENDANTS

192. Plaintiffs repeat and reallege paragraphs 1-191 as paragraph 192 of this Count.

193. The Illinois Consumer Fraud and Deceptive Business Practices Act ("ICFA") makes it unlawful for a person or business to use "unfair or deceptive acts or practices, including but not limited to the use or employment of any deception, fraud, false pretense, false promise, misrepresentation or the concealment, suppression or omission of any material fact, with intent that others rely upon the concealment, suppression or omission of such material fact, . . . in the conduct of any trade or commerce," regardless of "whether any person has in fact been misled, deceived or damaged thereby." 815 ILCS 505/2.

194. The Manufacturing Defendants' practices as described in the Complaint are deceptive business practices that violate ICFA because the practices were and are intended to deceive consumers, and the practices occurred and continue to occur in the course of conduct involving trade and commerce in Lake County.

195. At all times relevant to this Complaint, Manufacturing Defendants, directly, through their control of third parties, and/or by aiding and abetting third parties, violated the IFCA by making and disseminating untrue, false, and misleading statements in Lake County to promote the sale of opioids in the County. In overstating the benefits of and evidence for the use

of opioids for chronic pain and understating their very serious risks, including the risk of addiction; in disseminating misleading information regarding the appropriateness of their opioids, Manufacturing Defendants have engaged in misrepresentations, deception, and knowing omissions of material fact. Defendants Purdue and Endo have also engaged in misrepresentations, deception, and knowing omissions of material fact in falsely promoting abuse-deterrent formulations as reducing abuse; as well as, in the case of Purdue, in falsely claiming that OxyContin provides 12 hours of relief.

196. These untrue, false, and misleading statements included, but were not limited to:

a. Defendants' claims that the risks of long-term opioid use, especially the risk of addiction were overblown;

b. Defendants' claims that signs of addiction were "pseudoaddiction" reflecting undertreated pain, and should be responded to with more opioids;

c. Defendants' claims that screening tools effectively prevent addiction;

d. Defendants' claims that evidence supports the long-term use of opioids for chronic pain;

e. Defendants' claims that chronic opioid therapy would improve patients' function and quality of life;

f. Purdue's and Endo's claims that abuse-deterrent opioids reduce tampering and abuse; and

g. Purdue's claims OxyContin provides a full 12 hours of pain relief.

197. By engaging in the acts and practices alleged herein, Manufacturing Defendants omitted to state material facts, with the intent that others rely on their omissions or suppression of information, that they had a duty to disclose by virtue of Defendants' other representations, including, but not limited to, the following:

a. Opioids are highly addictive and may result in overdose or death;

b. No credible scientific evidence supports the use of screening tools as a strategy for reducing abuse or diversion;

c. High dose opioids subject the user to greater risks of addiction, other injury or death;

d. Exaggerating the risks of competing products, such as NSAIDs, while ignoring the risks of hyperalgesia, hormonal dysfunction, decline in immune function, mental clouding, confusion, and dizziness, increased falls and fractures in the elderly, neonatal abstinence syndrome, and potentially fatal interactions with alcohol or benzodiazepines;

e. Defendants' claims regarding the benefits of chronic opioid therapy lacked scientific support or were contrary to the scientific evidence;

f. Purdue's 12-hour OxyContin fails to last a full twelve hours in many patients; and

g. Purdue and Endo's abuse-deterrent formulations are not designed to address, and have no effect on, the most common route of abuse (oral abuse), can be defeated with relative ease; and may increase overall abuse.

198. Defendants' statements about the use of opioids to treat chronic pain were not supported by or were contrary to the scientific evidence.

199. At all times relevant to this Complaint, the Manufacturing Defendants directly, through their control of third parties, and by aiding and abetting third parties, made or caused to be disseminated the foregoing untrue, false and misleading statements, and material omissions, through an array of marketing channels, including but not limited to, in-person and other forms of detailing, conferences, teleconferences; or CMEs, publications in journals, brochures and other patient education materials.

200. The Manufacturing Defendants knew at the time of making or disseminating these misstatements and material omissions, or causing these misstatements and material omissions to be made or disseminated, that they were untrue, false, or misleading and therefore likely to deceive the public. In addition, the Defendants knew or should have known that their marketing

and promotional efforts created an untrue, false, and misleading impression of the risks, benefits, and superiority of opioids and intended that the County and its residents rely on the deception described in this Complaint.

201. In addition, at all times relevant to this Complaint, Manufacturing Defendants, directly, through their control of third parties, and/or by aiding and abetting third parties, violated the IFCA by engaging in unfair acts or practices to promote the sale and use of opioids to treat chronic pain. These acts or practices are unfair in that they offend public policy; are immoral, unethical, oppressive, or unscrupulous; and have resulted in substantial injury to Lake County and its residents that is not outweighed by any countervailing benefits to consumers or competition.

202. Manufacturing Defendants' unfair acts or practices include, but are not limited to:

a. Engaging in untrue, false, unsubstantiated, and misleading marketing, directly and with and through third parties in violation of 21 C.F.R. § 202.1(e), thereby causing their drugs to be misbranded;

b. Promoting other purported advantages of their opioid products, including but not limited to decreased risk of abuse, addiction, or withdrawal symptoms or their superiority to NSAIDs, without substantial scientific evidence to support their claims, in violation of FDA regulations, including 21 C.F.R. § 202.1(e);

c. Failing, despite the known, serious risks of addiction and adverse effects posed by opioids, to present a fair balance of benefit and risk information in their promotion of opioids, in violation of FDA regulations, including 21 C.F.R. § 202.1(e);

d. Deliberately using unbranded marketing to evade FDA oversight and rules prohibiting deceptive marketing;

e. Promoting their opioids for off-label uses in the case of Cephalon, by marketing Actiq and Fentora for treatment of non-cancer pain and/or for use in non-opioid-tolerant patients; and

f. Facilitating the abuse, addiction, and diversion of opioids, and causing injuries and fatalities from opioid overdoses, contrary to the programs and policies of the County to prevent and treat drug abuse,

> addiction, and diversion, including its diversion programs through A Way Out, its Alternative Prosecution Program, STOP probation program, and its specialty courts, its provision of services to treat addiction and prevent fatal overdoses and to collect unused medications, among other efforts.

203. Manufacturing Defendants engaged in these practices both directly and through the KOLs and Front Groups that they controlled and/or which they aided and abetted. Defendants were aware of the unfair conduct of the KOLs and Front Groups such as AAPM, AGS, and APS, and yet Manufacturing Defendants provided them substantial assistance and encouragement by helping them engage in the unfair practices. Manufacturing Defendants also substantially encouraged the unfair practices by providing the Front Groups and KOLs with funding and technical support for the shared purpose of issuing unfair, pro-opioid messaging.

204. Manufacturing Defendants' promotional practices as described above offend deep-seated public policies. As the Illinois legislature has decreed, "drug addiction [is] among the most serious health problems facing the people of the State of Illinois."[52] Nevertheless, by engaging in the conduct alleged above, Manufacturing Defendants actively worked to conceal the risk of addiction related to opioids from Illinois patients and prescribers in the hopes of selling greater quantities of their dangerous drugs. Manufacturing Defendants also worked to undermine public policy, enshrined by regulations contained in state and federal law, that is aimed at ensuring honest marketing and safe and appropriate use of pharmaceutical drugs. Their efforts likewise undermined the State's public policy of requiring manufacturers and distributors of controlled substances to maintain effective controls against diversion, as well as the County's

[52] 745 ILCS 35/2.

own policy of preventing and combating serious public health threats, including the opioid epidemic.[53]

205. Manufacturing Defendants' conduct also was oppressive to both patients and prescribers. Patients are laypersons who put their trust in physicians to appropriately convey and balance the risks and benefits of various treatment options. Physicians, in turn, are inclined to trust the advice of KOLs, front groups, and other seemingly independent sources of objective medical information. By engaging in the conduct described above, Defendants co-opted the sources reasonable physicians relied upon to convince those physicians that the risks related to opioids were minimal, that the benefits were substantial, and—as a result—that opioids were medically necessary to treat their patients' chronic pain. Manufacturing Defendants deliberately targeted non-specialist physicians and non-physician prescribers, who lacked the time and expertise to evaluate their deceptive claims. This is even more true of the patients who were both the subject and object of Manufacturing Defendants' marketing; patients have little ability to independently evaluate the medical necessity of the treatments they are prescribed and rely on the judgment of their physicians instead—the same judgment that was compromised by Manufacturing Defendants' unlawful conduct.

206. Finally, Defendants' conduct has caused substantial, indeed grievous, injury to Lake County and its residents. The staggering rates of opioid use, abuse, and addiction resulting from Manufacturing Defendants' marketing efforts have caused substantial injury to Lake County and its residents, including, but not limited to:

a. Nationally, upwards of 30% of all adults have used opioids, with the vast majority of the use stemming from prescribing for chronic pain conditions.

[53] *See* 720 ILCS 570/201 & 570/303.

b. A substantial number of Lake County residents prescribed opioids long-term for chronic pain have experienced the life-upending effects of addiction, abuse, misuse, and overdose. For those who can stop taking narcotic opioids, there are years of struggling with the pull of the drugs and the fear of relapse (and often relapse itself), counseling sessions, or lining up each morning for daily maintenance drugs. And those who cannot overcome the need for opioids must deal with the compulsive use of and need for opioids, the haziness when they are on the drugs, and the nearly constant struggle to maintain their supplies of the drugs, whatever the cost. Both groups face a dramatically heightened risk of serious injury or death and sometimes an unrecoverable toll on their health, work, and family.

c. Lake County residents who have never taken opioids also have also been injured. Many have endured both the emotional and financial costs of caring for loved ones addicted to or injured by opioids, and the loss of companionship, wages, or other support from family members who have used, abused, become addicted to, overdosed on, or been killed by opioids. Infants born to mothers who abuse opioids have suffered neonatal abstinence syndrome.

d. Health care costs have been incurred due to the prescription of opioids for chronic pain and the treatment of opioids' adverse effects, including addiction and overdose.

e. Manufacturing Defendants' success in extending the market for opioids to new patients and chronic conditions has also created an abundance of drugs available for criminal use and fueled a new wave of addiction, abuse, and injury. Manufacturing Defendants' scheme created both ends of a new secondary market for opioids—providing both the supply of narcotics to sell and the demand of addicts to buy them.

f. This demand also has created additional illicit markets in other opiates, particularly heroin. Patients addicted to opioids frequently migrate to lower-cost heroin, with the serious personal costs that accompany their use of unlawful drugs.

g. All of this has caused substantial injuries to consumers—in lives lost; addictions endured; the creation of an illicit drug market and all its concomitant crime and costs; unrealized economic productivity; and broken lives, families, and homes.

207. The profound injuries to Lake County and its residents are not outweighed by any countervailing benefits to consumers or competition since there is no benefit from the deceptive

marketing of these narcotic drugs. Moreover, no public policy justifies Manufacturing Defendants' conduct in overstating the benefits, denying or downplaying the risks, and misrepresenting the superiority of opioids for chronic pain, which deprived patients and doctors in Lake County of the honest and complete information they need to make informed choices about their treatment. In light of this campaign of misinformation (and especially given the addictive nature of these drugs), Lake County and its consumers could not reasonably have avoided their injuries.

208. All of this conduct, separately and collectively, was intended to deceive Lake County consumers who used or paid for opioids for chronic pain; Lake County physicians who prescribed opioids to consumers to treat chronic pain; and Lake County payors, including Lake County, who purchased, or covered the purchase of, opioids for chronic pain. Manufacturing Defendants engaged in the violations alleged in this Count with the intent to defraud.

209. As a direct result of the foregoing acts and practices, the Defendants have received, or will receive, income, profits, and other benefits, which they would not have received if they had not engaged in the violations of ICFA as described in this Complaint.

210. Because Defendants' unbranded marketing caused the doctors to prescribe and payors, including Lake County, to cover the long-term opioid treatment using opioids manufactured or distributed by other drug makers, Defendants caused and are responsible for those costs and claims, as well.

211. In addition, 815 ILCS 505/7 specifically allows the State's Attorney of Lake County to bring this claim for a penalty for each violation by the Defendants.

212. By reason of Manufacturing Defendants' unlawful acts, Lake County has been damaged and continues to be damaged, in a substantial amount to be determined at trial.

WHEREFORE, PLAINTIFFS respectfully request that this Court enter an order (a) awarding judgment in their favor and against Manufacturing Defendants on Count I of the Complaint; (b) enjoining Defendants from performing or proposing to perform any acts in violation of the IFCA; (c) compelling Manufacturing Defendants to pay restitution to the County; (d) compelling Manufacturing Defendants to pay civil penalties up to $50,000 per violation pursuant to 815 ILCS 505/7(b); (e) compelling Manufacturing Defendants to pay additional civil penalties up to $10,000 per violation for each violation committed against a person 65 years of age or older pursuant to 815 ILCS 505/7(c); (f) requiring Defendants to disgorge ill-gotten profits and providing such additional relief as may be appropriate to deter, prevent, or compensate for Manufacturing Defendants' violations of law; (g) compelling Manufacturing Defendants to pay the cost of the suit, including attorneys' fees and interest; and (h) awarding Plaintiffs such other, further, and different relief as this Honorable Court may deem just.

COUNT II

DECEPTIVE TRADE PRACTICES

VIOLATIONS OF 815 ILCS 510/1 *ET SEQ.*

AGAINST ALL DEFENDANTS

213. Plaintiffs repeat and reallege paragraphs 1-212 as paragraph 213 of this Count..

214. Section 2(a) of the Illinois Uniform Deceptive Trade Practices Act ("UDTPA") provides that:

> A person engages in a deceptive trade practice when, in the course of his or her business, vocation, or occupation, the person: . . .
>
> (2) causes likelihood of confusion or of misunderstanding as to the source, sponsorship, approval, or certification of goods or services; . . .

> (3) causes likelihood of confusion or of misunderstanding as to affiliation, connection, or association with or certification by another; . . .
>
> (5) represents that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation, or connection that he or she does not have; . . .
>
> (7) represents that goods or services are of a particular standard, quality, or grade or that goods are a particular style or model, if they are of another;
>
> (8) disparages the goods, services, or business of another by false or misleading representation of fact; . . .
>
> (12) engages in any other conduct which similarly creates a likelihood of confusion or misunderstanding.

215. To prevail in an action under the UDTPA, a plaintiff need not prove competition between the parties or actual confusion or misunderstanding. 815 ILCS 510/2(b).

216. Defendants have violated the UDTPA because they engaged in deceptive trade practices and engaged in conduct that created a likelihood of confusion or misunderstanding. Manufacturing Defendants caused a likelihood of confusion or misunderstanding as to the source or sponsorship, association with, or certification by another of their unbranded advertising. Manufacturing Defendants and Front Group Defendants alike violated the UDTPA in representing that opioids have characteristics, ingredients, qualities, or benefits that they do not have, such as low risk of addiction, functional improvement for chronic pain patients, abuse-deterrence, of 12-hours of pain relief, or were of a standard or quality when they were not. Manufacturing Defendants also disparaged NSAIDs and non-abuse deterrent opioids by false or misleading representations of fact.

217. Specifically, misrepresentations include, but are not limited to:

a. Defendants' claims that the risks of long-term opioid use, especially the risk of addiction were overblown;

b. Manufacturing Defendants' overstatement of the risks of NSAIDs, when compared to opioids;

c. Defendants' claims that evidence supports the long-term use of opioids for chronic pain;

d. Defendants' claims that chronic opioid therapy would improve patients' function and quality of life;

e. Purdue's and Endo's claims that abuse-deterrent opioids prevent tampering and abuse; and

f. Purdue's claims OxyContin provides a full 12 hours of pain relief.

218. By engaging in the acts and practices alleged herein, Defendants omitted material facts, with the intent that others rely on their omissions or suppression of information, that they had a duty to disclose by virtue of Defendants' other representations, including, but not limited to, the following:

a. opioids are highly addictive and may result in overdose or death;

b. no credible scientific evidence supports the use of screening tools as a strategy for reducing abuse or diversion;

c. high dose opioids subject the user to greater risks of addiction, other injury, or death;

d. the risks of hyperalgesia, hormonal dysfunction, decline in immune function, mental clouding, confusion, and dizziness, increased falls and fractures in the elderly, neonatal abstinence syndrome, and potentially fatal interactions with alcohol or benzodiazepines, particularly while exaggerating the risks of competing products, such as NSAIDs;

e. claims regarding the benefits of chronic opioid therapy lacked scientific support or were contrary to the scientific evidence;

f. Purdue's 12-hour OxyContin fails to last a full twelve hours in many patients;

g. Purdue and Endo's abuse-deterrent formulations are not designed to address, and have no effect on, the most common route of abuse (oral abuse), can be defeated with relative ease; and may increase overall abuse; and

h. Manufacturing Defendants' failed to disclose their financial ties to and role in connection with KOLs and Front Groups.

219. Defendants' statements about the use of opioids to treat chronic pain were not supported by or were contrary to the scientific evidence.

220. The County and its residents are likely to be damaged, and have been damaged, by the deceptive trade practices alleged in this Complaint.

WHEREFORE, PLAINTIFFS respectfully request that this Court enter an order (a) awarding judgment in their favor and against Defendants on Count II of the Complaint; (b) enjoining Defendants from performing or proposing to perform any acts in violation of the UDTPA; (c) compelling Defendants to pay the cost of the suit, including attorneys' fees and interest; and (d) awarding Plaintiffs such other, further, and different relief as this Honorable Court may deem just.

COUNT III

CONSUMER FRAUD—UNFAIR COMPETITION AND DECEPTIVE TRADE PRACTICES

VIOLATIONS OF 815 ILCS 505/1 *ET SEQ.*

PURSUANT TO 815 ILCS 505/1

AGAINST MANUFACTURING DEFENDANTS

221. Plaintiffs repeat and reallege paragraphs 1-220 as paragraph 221 of this Count.

222. The IFCA makes it unlawful for a person to engage in "[u]nfair methods of competition," and the use "of any practice described in Section 2 of the 'Uniform Deceptive Trade Practices Act,' ["UDTPA"] approved August 5, 1965" is a violation of the IFCA. 815 ILCS 505/2.

223. At all times relevant to this Complaint, the Manufacturing Defendants, directly, through their control of third parties, and/or by aiding and abetting third parties, violated the IFCA and UDTPA by making and disseminating untrue, false, and misleading statements in Lake County to promote the sale of opioids in the County.

224. Manufacturing Defendants caused a likelihood of confusion or misunderstanding as to the source or sponsorship of their unbranded advertising, in overstating the risks of NSAIDs, and in representing that opioids have characteristics, ingredients, quality, or benefits that they do not have, such as low risk of addiction and functional improvement to chronic pain patients, and in the case of Defendants Purdue and Endo, that abuse-deterrent features that made the drugs safer, impossible to abuse, or less likely to be abused or diverted, and, in the case of Purdue, that 12-hour OxyContin would reliably provide 12-hour pain relief.

225. These material misstatements and omissions include, but are not limited to, those set forth in Paragraphs 196-197 and 217-218 above.

226. Manufacturing Defendants willfully engaged in the acts or practices alleged in this Complaint knowing them to be deceptive and with the intent to defraud.

227. All of this conduct, separately and collectively, was intended to deceive Illinois consumers who used or paid for opioids for chronic pain; Illinois physicians who prescribed opioids to consumers to treat chronic pain; and Illinois payors, including Lake County, which purchased, or covered the purchase of, opioids for chronic pain. Manufacturing Defendants engaged in the violations alleged in this Count with the intent to defraud.

228. As a direct result of the foregoing acts and practices, Manufacturing Defendants have received, or will receive, income, profits, and other benefits, which they would not have received if they had not engaged in the violations of ICFA as described in this Complaint.

229. Because Manufacturing Defendants' deceptive marketing caused the doctors to prescribe and Lake County to pay for long-term opioid treatment using opioids manufactured or distributed by other drug makes, Manufacturing Defendants caused and are responsible for those costs and claims, as well.

230. In addition, 815 ILCS 505/7 specifically allows the State's Attorney to bring this claim for a penalty for each violation by the Manufacturing Defendants.

231. By reason of Manufacturing Defendants' unlawful acts, Lake County has been damaged and continue to be damaged, in a substantial amount to be determined at trial.

WHEREFORE, PLAINTIFFS respectfully request that this Court enter an order (a) awarding judgment in their favor and against Manufacturing Defendants on Count III of the Complaint; (b) enjoining Defendants from performing or proposing to perform any acts in violation of the IFCA; (c) compelling Manufacturing Defendants to pay restitution to the County; (d) compelling Manufacturing Defendants to pay civil penalties up to $50,000 per violation pursuant to 815 ILCS 505/7(b); (e) compelling Manufacturing Defendants to pay additional civil penalties up to $10,000 per violation for each violation committed against a person 65 years of age or older pursuant to 815 ILCS 505/7(c); (f) requiring Defendants to disgorge ill-gotten profits and providing such additional relief as may be appropriate to deter, prevent, or compensate for Manufacturing Defendants' violation of law; (g) compelling Manufacturing Defendants to pay the cost of the suit, including attorneys' fees and interest; and (h) awarding Plaintiffs such other, further, and different relief as this Honorable Court may deem just.

COUNT IV

CONSUMER FRAUD—UNFAIR COMPETITION AND DECEPTIVE TRADE PRACTICES

VIOLATIONS OF 815 ILCS 505/1 *ET SEQ.*

PURSUANT TO 815 ILCS 505/7

AGAINST FRONT GROUP DEFENDANTS

232. Plaintiffs repeat and reallege paragraphs 1-231 as paragraph 232 of this Count.

233. In overstating the benefits of and evidence for the use of opioids for chronic pain and understating their very serious risks, including the risk of addiction; in disseminating misleading information regarding the appropriateness of their opioids for certain conditions, and in falsely portraying their statements as those of independent, unbiased third-parties, the Front Group Defendants have engaged in misrepresentations, deception, and knowing omissions of material fact.

234. These material misrepresentations and omissions include, but are not limited to, those set forth in Counts I and II above.

235. As a direct and proximate result of these violations of the IFCA, the County has suffered and continues to face injury and damage.

WHEREFORE, PLAINTIFFS respectfully request that this Court enter an order (a) awarding judgment in their favor and against the Front Group Defendants on Count IV of the Complaint; (b) enjoining the Front Group Defendants from performing or proposing to perform any acts in violation of the IFCA; and (c) awarding Plaintiffs such other, further, and different relief as this Honorable Court may deem just.

COUNT V

INSURANCE FRAUD

VIOLATIONS OF 720 ILCS 5/17-10.5

AGAINST MANUFACTURING DEFENDANTS

236. Plaintiffs repeat and reallege paragraphs 1-235 as paragraph 236 of this Count.

237. 720 ILCS § 5/17-10.5(a)(1) provides in pertinent part:

> (1) A person commits insurance fraud when he or she knowingly obtains, attempts to obtain, or causes to be obtained, by deception, control over the property of an insurance company or self-insured entity by the making of a false claim or by causing a false claim to be made on any policy of insurance issued by an insurance company or by the making of a false claim or by causing a false claim to be made to a self-insured entity, intending to deprive an insurance company or self-insured entity permanently of the use and benefit of that property.

238. 720 ILCS § 5/17-10.5(e)(1) provides in pertinent part:

> Civil damages for insurance fraud. A person who knowingly obtains, attempts to obtain, or causes to be obtained, by deception, control over the property of any insurance company by the making of a false claim or by causing a false claim to be made on a policy of insurance issued by an insurance company, or by the making of a false claim or by causing a false claim to be made to a self-insured entity, intending to deprive an insurance company or self-insured entity permanently of the use and benefit of that property, shall be civilly liable to the insurance company or self-insured entity that paid the claim or against whom the claim was made or to the subrogee of that insurance company or self- insured entity in an amount equal to either 3 times the value of the property wrongfully obtained or, if no property was wrongfully obtained, twice the value of the property attempted to be obtained, whichever amount is greater, plus reasonable attorney's fees.

239. At all times relevant to this Complaint, Manufacturing Defendants, directly, through their control of third parties, and by acting in concert with third parties: (a) knowingly caused false claims to be made to the County's health plan, which is self-insured; and (b) knowingly obtained or caused to be obtained through deception the property of the County in

payments for those false claims. Manufacturing Defendants' scheme caused prescribers to write prescriptions for opioids to treat chronic pain that were presented to the County's health plan for payment. Therefore, each claim for reimbursement to the County for chronic opioid therapy is the direct result of Manufacturing Defendants' marketing, which presented to prescribers false information about the risks, benefits, and superiority of opioids for the long-term treatment of pain.

240. Further, the County's health plan only covers the cost of services, tests, and prescription drugs that are medically necessary, reasonably required, and prescribed for an FDA-approved use. Doctors, pharmacists, other health care providers, and/or other agents of the health plan expressly or impliedly certified to the County that opioids were medically necessary and reasonably required to treat chronic pain because they were influenced by the false and misleading statements disseminated by Manufacturing Defendants about the risks, benefits, and superiority of opioids for chronic pain. Moreover, many of the prescriptions written by physicians or other health care providers and/or authorized by the health plan, and submitted to the County were for uses that were misbranded and/or for off-label uses not approved by the FDA.

241. The misrepresentations were material because if the Plaintiffs had known of the false statements disseminated by Manufacturing Defendants and that doctors, pharmacies, other health care providers, and/or the health plan certified and/or determined that opioids were medically necessary and reasonably required based on those false statements, the Plaintiffs would have refused to authorize payment for opioid prescriptions. The County is a self-insured entity and directly covers the cost of prescription drugs and other medical services for County employees and retirees.

242. By virtue of the above-described acts, Manufacturing Defendants knowingly made, used, or caused to be made false claims with the intent to induce the County to approve and pay such false and fraudulent claims.

243. By virtue of the above-described acts, Manufacturing Defendants acted in concert with third party Front Groups and KOLs to make misleading statements about the risks, benefits, and superiority of opioids to treat chronic pain. Manufacturing Defendants were aware of the misleading nature of the misstatements and material omissions made by KOLs and Front Groups, and yet Manufacturing Defendants provided them substantial assistance and encouragement by helping them develop, refine and promote these misstatements and material omissions and distributing them to a broader audience. Manufacturing Defendants also substantially encouraged the dissemination of these misstatements and material omissions by providing the Front Groups and KOLs with funding and technical support for the shared purpose of issuing misleading, pro-opioid messaging. Manufacturing Defendants knew or should have known that these marketing and promotional efforts created an untrue, false, and misleading impression about the risks, benefits, and superiority of opioids for chronic pain and would result in the submission of false insurance claims for opioid prescriptions written to treat chronic pain.

244. By reason of Manufacturing Defendants' insurance fraud, the County has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Since January 1, 2013, the County has spent more than $331,000to pay for more than 9,800 prescriptions and suffered additional damages for the costs of providing and using opioids long-term to treat chronic pain, including, but not limited to, funding for substance-abuse treatment.

245. Because Manufacturing Defendants' unbranded marketing caused the doctors to prescribe and the City to pay for long-term opioid treatment using opioids manufactured or

distributed by other drug makers, Defendants caused and are responsible for those costs and claims, as well.

WHEREFORE, PLAINTIFFS respectfully request that this Court enter an order (a) awarding judgment in its favor and against Defendants on Count V of the Complaint; (b) compelling Manufacturing Defendants to pay three times any money acquired as a result of Manufacturing Defendants' fraud; (c) compelling Manufacturing Defendants to pay the cost of the suit, including attorneys' fees and interest; and (d) awarding Plaintiffs such other, further, and different relief as this Honorable Court may deem just.

WHEREFORE, PLAINTIFFS respectfully request that this Court enter an order (a) awarding judgment in their favor and against Defendants on Count V of the Complaint; (b) compelling Manufacturing Defendants to pay three times any money acquired as a result of Manufacturing Defendants' fraud; (c) compelling Manufacturing Defendants to pay the cost of the suit, including attorneys' fees and interest; and (d) awarding Plaintiffs such other, further, and different relief as this Honorable Court may deem just.

COUNT VI

FRAUD

AGAINST MANUFACTURING DEFENDANTS

246. Plaintiffs repeat and reallege paragraphs 1-245 as paragraph 246 of this Count.

247. The elements to state a cause of action for common law fraud are: "(1) a statement by defendant; (2) of a material nature as opposed to opinion; (3) that was untrue; (4) that was known or believed by the speaker to be untrue or made in culpable ignorance of its truth or falsity; (5) that was relied on by the plaintiff to his detriment; (6) made for the purpose of inducing reliance; and (7) such reliance led to the plaintiff's injury. *Olendorf v. General Motors*

Corp., 322 Ill.App.3d 825, 831 (Ill. App. 2001) (internal quotation and citation omitted). All such essential elements exist here.

248. As alleged herein, Manufacturing Defendants made false statements in overstating the benefits of and evidence for the use of opioids for chronic pain and understating their very serious risks, including the risk of addiction; in disseminating misleading information regarding the appropriateness of their opioids for certain conditions, and in falsely portraying their efforts or commitment to rein in the diversion and abuse of opioids Defendants have engaged in misrepresentations, deception, and knowing omissions of material fact. Defendants Purdue and Endo have also engaged in misrepresentations, deception, and knowing omissions of material fact in falsely promoting abuse-deterrent formulations as reducing abuse; as well as, in the case of Purdue, in falsely claiming that OxyContin provides 12 hours of relief.

249. As alleged herein, the Manufacturing Defendants engaged in false representations and concealments of material fact, including but not limited to the material misrepresentations described in Paragraphs 196-197 and 217-218 above.

250. As alleged herein, Manufacturing Defendants knowingly and/or intentionally made representations that were false. Manufacturing Defendants had a duty to disclose material facts and concealed them. These false representations and concealed facts were material to the conduct and actions at issue. Manufacturing Defendants made these false representations and concealed facts with knowledge of the falsity of their representations, and did so with the intent of misleading Plaintiffs, the public, and persons on whom Plaintiffs relied.

251. These false representations and concealments were reasonably calculated to deceive Plaintiffs and the physicians who prescribed opioids for persons in the County, were made with the intent to deceive, and did in fact deceive these persons and Plaintiffs.

252. Plaintiffs, including the residents of the County, and the physicians who prescribed opioids reasonably relied on these false representations and concealments of material fact.

253. Plaintiffs justifiably relied on Manufacturing Defendants' representations and/or concealments, both directly and indirectly. Plaintiffs' injuries were proximately caused by this reliance.

254. The injuries alleged by Plaintiffs herein were sustained as a direct and proximate cause of Manufacturing Defendants' fraudulent conduct.

255. Plaintiffs seek economic losses (direct, incidental, or consequential pecuniary losses) resulting from Defendants' fraudulent activity. Plaintiffs do not seek damages for the wrongful death, physical personal injury, serious emotional distress, or any physical damage to property caused by Defendants' actions.

256. Plaintiffs seek all legal and equitable relief as allowed by law, except as expressly disavowed herein, including *inter alia* injunctive relief, restitution, disgorgement of profits.

WHEREFORE, PLAINTIFFS respectfully request that this Court enter an order (a) awarding judgment in their favor and against Defendants on Count VI of the Complaint; (b) compelling Manufacturing Defendants to pay damages for Manufacturing Defendants' fraud; (c) compelling Manufacturing Defendants to pay the cost of the suit, including attorneys' fees and interest; and (d) awarding Plaintiffs such other, further, and different relief as this Honorable Court may deem just.

COUNT VII

FRAUDULENT MISREPRESENTATION

AGAINST MANUFACTURING DEFENDANTS

257. Plaintiffs repeat and reallege paragraphs 1-256 as paragraph 257 of this Count.

258. The elements of a fraudulent misrepresentation claim are: "(1) a false statement of material fact; (2) knowledge or belief of the falsity by the person making it; (3) intention to induce the other party to act; (4) action by the other party in reliance on the truth of the statements; and (5) damage to the other party resulting from such reliance." *Guvenoz v. Target Corp.*, 30 N.E.3d 404, 423 (Ill. App. 2015) (internal quotation and citation omitted). All such essential elements exist here.

259. As alleged herein, Manufacturing Defendants made false statements in overstating the benefits of and evidence for the use of opioids for chronic pain and understating their very serious risks, including the risk of addiction; in disseminating misleading information regarding the appropriateness of their opioids for certain conditions, and in falsely portraying their efforts or commitment to rein in the diversion and abuse of opioids Defendants have engaged in misrepresentations, deception, and knowing omissions of material fact. Defendants Purdue and Endo have also engaged in misrepresentations, deception, and knowing omissions of material fact in falsely promoting abuse-deterrent formulations as reducing abuse; as well as, in the case of Purdue, in falsely claiming that OxyContin provides 12 hours of relief.

260. As alleged herein, the Manufacturing Defendants engaged in false representations and concealments of material fact, including but not limited to the material misrepresentations described in Paragraphs 196-197 and 217-218 above.

261. As alleged herein, Manufacturing Defendants knowingly and/or intentionally made representations that were false. Manufacturing Defendants had a duty to disclose material facts and concealed them. These false representations and concealed facts were material to the conduct and actions at issue. Manufacturing Defendants made these false representations and concealed facts with knowledge of the falsity of their representations, and did so with the intent of misleading Plaintiffs, the public, and persons on whom Plaintiffs relied.

262. These false representations and concealments were reasonably calculated to deceive Plaintiffs and the physicians who prescribed opioids for persons in the County, were made with the intent to deceive, and did in fact deceive these persons and Plaintiffs.

263. Plaintiffs, including the residents of the County, and the physicians who prescribed opioids reasonably relied on these false representations and concealments of material fact.

264. Plaintiffs justifiably relied on Manufacturing Defendants' representations and/or concealments, both directly and indirectly. Plaintiffs' injuries were proximately caused by this reliance.

265. The injuries alleged by Plaintiffs herein were sustained as a direct and proximate cause of Manufacturing Defendants' fraudulent conduct.

266. Plaintiffs seek economic losses (direct, incidental, or consequential pecuniary losses) resulting from Defendants' fraudulent misrepresentations and fraudulent concealment. Plaintiffs do not seek damages for the wrongful death, physical personal injury, serious emotional distress, or any physical damage to property caused by Defendants' actions.

267. Plaintiffs seek all legal and equitable relief as allowed by law, except as expressly disavowed herein, including inter alia injunctive relief, restitution, disgorgement of profits.

WHEREFORE, PLAINTIFFS respectfully request that this Court enter an order (a) awarding judgment in their favor and against Defendants on Count VII of the Complaint; (b) compelling Manufacturing Defendants to pay damages for Manufacturing Defendants' fraudulent misrepresentations and fraudulent concealment; (c) compelling Manufacturing Defendants to pay the cost of the suit, including attorneys' fees and interest; and (d) awarding Plaintiffs such other, further, and different relief as this Honorable Court may deem just.

COUNT VIII

DRUG DEALER LIABILITY ACT

VIOLATIONS OF 740 ILCS 57/5 *ET SEQ.* AGAINST MANUFACTURING DEFENDANTS

268. Plaintiffs repeat and reallege paragraphs 1-267 as paragraph 268 of this Count.

269. Illinois' Drug Dealer Liability Act provides a civil remedy for damages to persons, including governmental entities and others who pay for drug treatment or employee assistance programs, in a community injured as a result of illegal drug use. 740 ILCS 57/5.

270. The statute recognizes that "[e]very community in the country is affected by the marketing and distribution of illegal drugs," and "[t]he civil justice system can provide an avenue of compensation for those who have suffered harm as a result of the marketing and distribution of illegal drugs." 740 ILCS 57/10.

271. Section 20 of the Illinois Drug Dealer Liability Act provides, in pertinent part, that, "[a] person who knowingly participates in the illegal drug market within this State is liable for civil damages as provided in this Act. A person may recover damages under this Act for injury resulting from an individual's use of an illegal drug." 740 ILCS 57/20(a).

272. The statute provides that a governmental entity that funds a drug treatment program or employee assistance program for an individual drug user or otherwise expended

money on behalf of an individual drug user, may bring an action for damages caused by an individual's use of an illegal drug, as can any person injured as a result of the willful, reckless, or negligent actions of an individual drug user. 740 ILCS 57/25(a).

273. A person entitled to bring such an action may seek damages from:

> (1) A person who knowingly distributed, or knowingly participated in the chain of distribution of, an illegal drug that was actually used by the individual drug user.
>
> (2) A person who knowingly participated in the illegal drug market if:
>
> (A) the place of illegal drug activity by the individual drug user is within the illegal drug market target community of the defendant;
>
> (B) the defendant's participation in the illegal drug market was connected with the same type of illegal drug used by the individual drug user; and
>
> (C) the defendant participated in the illegal drug market at any time during the individual drug user's period of illegal drug use.

274. Under 740 ILCS 57/25:

> A person entitled to bring an action under this Section may recover all of the following damages:
>
> (1) economic damages, including, but not limited to, the cost of treatment and rehabilitation, medical expenses, loss of economic or educational potential, loss of productivity, absenteeism, support expenses, accidents or injury, and any other pecuniary loss proximately caused by the illegal drug use; . . .
>
> (3) exemplary damages;
>
> (4) reasonable attorneys' fees;
>
> (5) costs of suit, including, but not limited to, reasonable expenses for expert testimony.

740 ILCS 57/25(c).

275. Lake County funds drug treatment for individuals' use of illegal drugs, and has been damaged by Manufacturing Defendants actions deceptively promoting opioids, in violation of state law, as laid out above..

276. Manufacturing Defendants knowingly distributed, or knowingly participated in the chain of distribution of, an illegal drug that was actually used by individual drug users in Lake County.

277. Manufacturing Defendants profited from the illegal drug market in Illinois, including in Plaintiffs' community.

278. As a direct result of Manufacturing Defendants' actions alleged in this Count, Plaintiffs have suffered injury and damages.

WHEREFORE, PLAINTIFFS respectfully request that this Court enter an order (a) awarding judgment in their favor and against Defendants on Count VIII of the Complaint; (b) compelling Manufacturing Defendants to pay damages for Manufacturing Defendants' violations of the Illinois Drug Dealer Liability Act, including, but not limited to, the cost of treatment and rehabilitation, medical expenses, loss of economic or educational potential, loss of productivity, absenteeism, support expenses, accidents or injury, and other pecuniary loss; (c) compelling Manufacturing Defendants to pay exemplary damages; (d) compelling Manufacturing Defendants to pay the cost of the suit, including attorneys' fees and interest; and (d) awarding Plaintiffs such other, further, and different relief as this Honorable Court may deem just.

COUNT IX

UNJUST ENRICHMENT

VIOLATIONS OF THE COMMON LAW PROHIBITION ON UNJUST ENRICHMENT AGAINST MANUFACTURING DEFENDANTS

279. Plaintiffs repeat and reallege paragraphs 1-278 as paragraph 279 of this Count.

280. Defendants have unjustly retained a benefit to the County's detriment, and the Defendants' retention of the benefit violates the fundamental principles of justice, equity, and good conscience.

281. By illegally and deceptively promoting opioids to treat chronic pain, directly, through their control of third parties, and by acting in concert with third parties, Manufacturing Defendants have unjustly enriched themselves at the County's expense. The County has made payments for opioid prescriptions, and Manufacturing Defendants benefited from those payments. Because of their deceptive promotion of opioids, Manufacturing Defendants obtained enrichment they would not otherwise have obtained. The enrichment was without justification and the County lacks a remedy provided by law.

282. By reason of Defendants' unlawful acts, the County has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

WHEREFORE, PLAINTIFFS respectfully request that this Court enter an order (a) awarding judgment in their favor and against Manufacturing Defendants on Count VIX of the Complaint; (b) compelling Manufacturing Defendants to disgorge all unjust enrichment to the County; and (c) awarding such other, further, and different relief as this Honorable Court may deem just.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request the following relief:

A. A finding that by the acts alleged herein, Defendants violated the ICFA, 815 ILCS 505/1 and UDTPA, 815 ILCS 510/1 *et seq.*;

B. For an injunction permanently enjoining Defendants from engaging in acts and practices that violate the ICFA, 815 ILCS 505/1 and UDTPA, 815 ILCS 510/1 *et seq.*;

C. For an order compelling Manufacturing Defendants to pay civil penalties up to $50,000 per violation pursuant to 815 ILCS 505/7(b), and additional civil penalties up to $10,000 per violation for each violation committed against a person 65 years of age or older pursuant to 815 ILCS 505/7(c);

D. For an order directing Manufacturing Defendants to pay restitution of money acquired from the County as a result of the ICFA violations alleged in this Complaint;

E. A finding that by the acts alleged herein, the Manufacturing Defendants violated 720 ILCS 5/17-10.5(a)(1);

F. An order compelling Manufacturing Defendants to pay three times any money acquired as a result of Manufacturing Defendants' insurance fraud under 720 ILCS 5/17-10.5(a)(1);

G. A finding that by the acts alleged herein, the Manufacturing Defendants violated 740 ILCS 57/5 *et seq.*;

H. An award of compensatory damages against in an amount sufficient to fairly and completely compensate for all damages alleged herein;

I. Disgorgement of Manufacturing Defendants' unjust enrichment, benefits, and ill-gotten gains, plus interest, acquired as a result of the unlawful or wrongful conduct alleged herein pursuant to common law;

J. For punitive damages;

K. For costs, filing fees, pre and post judgment interest, and attorney's fees; and

L. For all other relief deemed just by this Court.

DATED: December 21, 2017

Respectfully submitted,

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